United States Department of Agriculture

Animal and Plant Health Inspection Service

Food Safety and Inspection Service

Procedure Manual for Bovine Spongiform Encephalopathy (BSE) Surveillance

August 2004

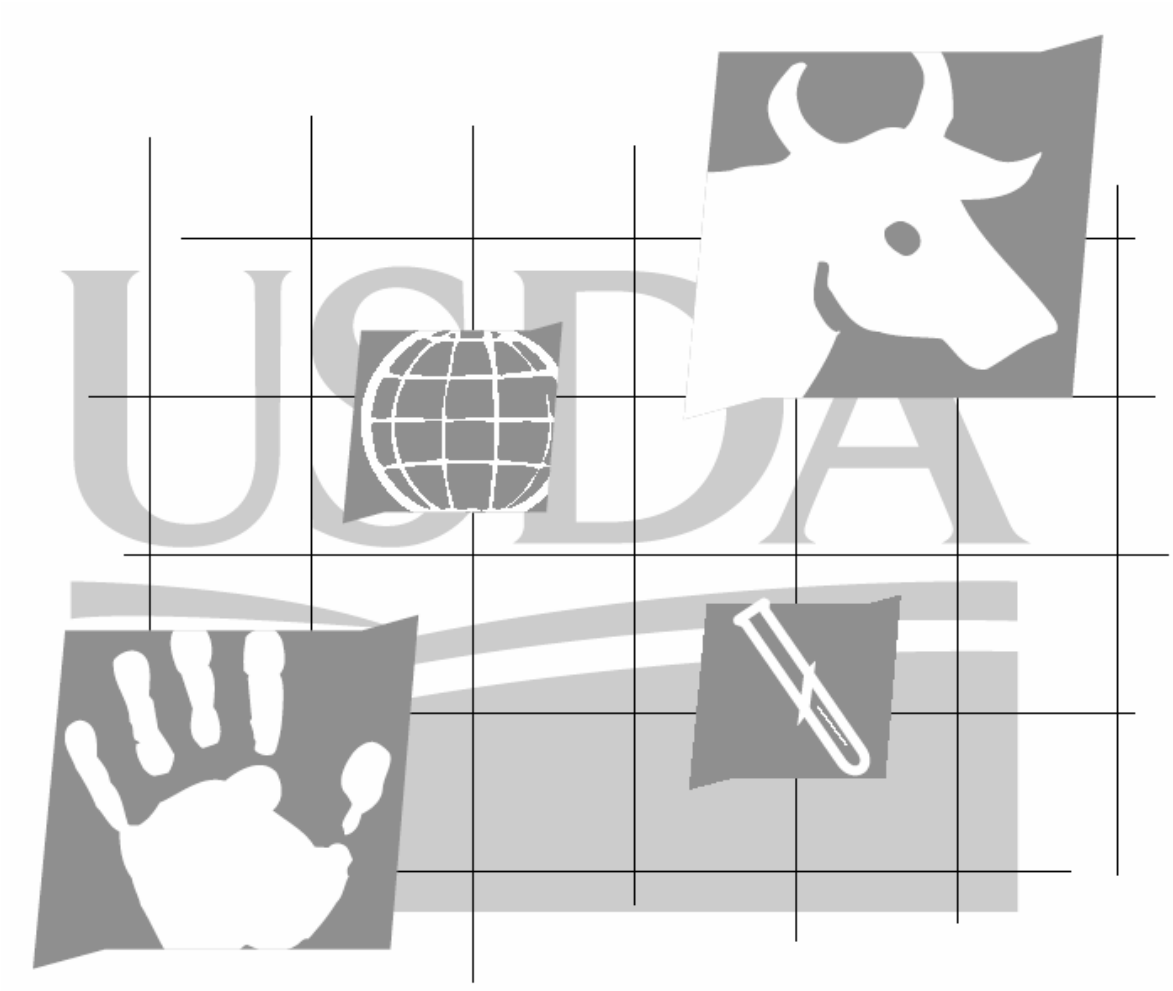


Table of Contents

Introduction

Purpose

This document describes the guidance and procedures for the national surveillance program for bovine spongiform encephalopathy (BSE) beginning in June 2004. The goal of the program is to test as many cattle as possible in the described targeted high-risk population over a 12-18 month period along with a sample of normal aged animals presented at slaughter. At the end of this period, APHIS and FSIS will evaluate the results and adjust future policies based on the evaluation.

The purpose of this document is to clarify:

- The objective of the overall survey and the objective for each of the three categories of animals to be sampled:
  - Cattle highly suspicious for BSE
  - Targeted high risk cattle
  - Normal adult cattle
- When to refer a highly suspicious for BSE animal to the Area Veterinarian-In-Charge (AVIC) for a possible Foreign Animal Disease (FAD) investigation
- Personal safety guidelines
- When and how to sample targeted high risk cattle
- When and how to sample apparently normal adult cattle
- What information to record about the sample
- How to ship the sample
- Where to ship the sample
- Communication protocols
- Disposal of the carcass and offal

In addition, a number of appendices give more detailed information:

If you need:	**Then see appendix**
VS Memo 580.16 on BSE surveillance procedures	A
The entire national BSE Surveillance Plan	B
Example of a state-specific plan	C
One page summary of the sampling procedures	D
Guidance on what a quality sample looks like	E
Contact information for APHIS, VS Area-Veterinarians-In-Charge	F
Instructions on filling out paper BSE submission forms and the Web versions of those forms	G
Information about the use of barcodes in shipping your sample	H

If you need:	**Then see appendix**
Information on determining the age of cattle	I
General background information about BSE	J
FSIS documents	K
Information USDA has sent to the media and made available to the public	L
Information about how FAD investigations are conducted	M

Surveillance Plan Overview

The Animal and Plant Health Inspection Service (APHIS), in cooperation with the Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA), has begun an intensive national BSE surveillance plan to determine whether BSE is actually present in the cattle population and if so, at what level. The goal is to test as many targeted high risk cattle as possible in a 12-18 month period. The three agencies will analyze the results and consider future actions. This plan also incorporates random sampling of clinically normal aged cattle at slaughter.

There are 3 categories of cattle to consider: 1) cattle highly suspicious for BSE, 2) cattle in the targeted high risk population, and 3) normal adult cattle presented for slaughter. Here are the surveillance objectives for those three categories:

1) Cattle Highly Suspicious for BSE

Cattle fit this category if the clinical signs of BSE are observed as described in Veterinary Services (VS) Memorandum 580.16 (Appendix A). These observations are usually made on the farm or at other locations where animals can be observed over a period if time. According to Office International des Epizooties (OIE) guidelines, with an estimated adult cattle population of 45,000,000 in the U.S., the minimum number of cattle in this category in 12-18 months is approximately 450.

All cattle that fit this category should be referred to the AVIC in your state (see Appendix F for a list of AVIC offices and contact information, or go to http://www.aphis.usda.gov/vs/ncie/pdf/vsavic.pdf). The AVIC or their designee will determine if a full FAD investigation is warranted and assign a Foreign Animal Disease Diagnostician (FADD) to collect a BSE sample. Note that the procedures for collecting a sample as part of an FAD investigation are different from the regular surveillance sampling procedures.

See Appendix M for a copy of VS Memorandum 580.4 that provides the guidance for conducting FAD investigations. The VS Memorandum 580.16 contains the details of the procedures for taking a sample as part of an FAD investigation.

2) Cattle in the Targeted High-Risk Population

The objective for this portion of the plan is to collect samples from as many adult cattle from the targeted high-risk population as possible in 12-18 months with an appropriate geographical representation. See pages 8 to 23 for instructions on collecting a sample.

3) Apparently normal adult cattle presented for slaughter

Plans are being developed for sampling several thousand adult, clinically normal slaughter cattle. The samples will be obtained from cattle going to the largest adult cattle slaughter plants, which handle approximately 86 percent of the adult cattle slaughtered annually in the United States. The largest volume plants are located in AZ, CA, GA, ID, MI, MN, MO, NC, NE, OH, PA, SC, SD, UT, TX, WA, and WI.

Sampling the Targeted High-Risk Cattle for BSE

If cattle are **not** highly suspicious for BSE yet show some of the signs described below, they are part of the targeted population for this survey:

Definition – Targeted Cattle Population

Age – Unless otherwise designated, samples should only be obtained from animals over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors. (See Appendix I for instructions on how to determine the age of cattle.)

Clinical Presentation Criteria

1. Downer / nonambulatory cattle – Cattle that cannot rise from a recumbent position (downer) or that cannot walk including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral columns, or metabolic conditions, as well as cattle that are severely weakened though they may be able to stand and walk for brief periods of time.

2. Central nervous system (CNS) signs and/or rabies negative – sample animals of any age:
   a. Diagnostic laboratories – samples submitted due to evidence of CNS clinical signs.
   b. Public health laboratories – rabies negative cases.
   c. Slaughter facilities – CNS antemortem condemns at slaughter, sampled by FSIS
   d. On-the-farm – CNS cattle that do not meet the criteria for an FAD investigation.

3. Cattle exhibiting other signs that may be associated with BSE – Cattle that were condemned or euthanized or that died as a result of a moribund condition, tetanus, emaciation, injuries, or non-ambulatory conditions.

4. Dead cattle – Any dead cattle where the specimen is of diagnostic quality and the cause of death and/or clinical signs prior to death, if known, do not preclude it from the targeted population.

Collection sites

Samples can be collected most efficiently and cost-effectively at concentration points. These are facilities where multiple animals or carcasses are collected, such as a rendering facility, a deadstock collection point, or a salvage (3D/4D) slaughter facility. While focusing efforts on these facilities will allow the highest number of samples to be collected within a defined time frame, samples may be collected at any site where targeted animals are located. In addition to those previously identified, this may include on the farm, state or federally inspected slaughter facilities, livestock markets, veterinary clinics, diagnostic laboratories, or any other facility as necessary.

There are special instructions for cattle condemned on ante-mortem inspection at slaughter:

Cattle condemned on ante-mortem inspection at slaughter (See Appendix K, page K14):

All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled.

All cattle, with the exception of veal calves (less than 400 pounds at slaughter,) condemned by FSIS upon antemortem inspection for any reason other than CNS will be sampled.

This sampling will be done on-site at the slaughter establishment unless documented, verifiable alternative arrangements for off-site sampling have been approved in advance. Sampling done on-site at the slaughter establishment will be done by FSIS personnel at federally inspected plants, and either APHIS or state personnel at state inspected plants. Sampling done through approved off-site arrangements will be done by APHIS personnel or their contractors.

Samples will be collected from these animals and submitted to the designated laboratory regardless of sample quality. Results from testing of cattle in this category will be provided; however, unless the samples are from cattle that meet the above definition of targeted samples, these data will not be included in the statistical analysis nor will they count toward our BSE surveillance sampling target.

Sampling Apparently Normal Adult Cattle Presented for Slaughter

Plans for this surveillance are still being finalized. Current draft protocols call for a total of 20,000 samples to be obtained from apparently normal adult (over 30 months old) cattle presented for slaughter at the largest adult cattle slaughter facilities. These facilities slaughter most of the adult cattle in this country.

Procedures for Obtaining and Submitting Samples from Targeted High-Risk and Apparently Normal Cattle

- ☐ **Collect the brain stem, including the obex.** Use a brain tissue spoon or other suitable device. Sampling spoons and tools will be provided by NVSL to sample collectors.

- ☐ **Prepare samples for shipping**. Sample collectors must evaluate the acceptability of the tissue sample. Samples that are taken from the wrong location or that are significantly autolyzed are not testable, and should not be submitted unless specific arrangements are made in advance. The only exception to this is for samples taken from cattle condemned as a result of an antemortem inspection. See Appendix E for guidance on taking and submitting a quality sample.

- ☐ **Complete forms for sample submissions.** Sample submitters must accurately record all relevant information on the USDA BSE Surveillance Submission Form, USDA BSE Surveillance Submission Continuation Form if used, and on each of the USDA BSE Surveillance Data Collection Forms. Enter this information on the electronic version of these forms – either on a tablet PC or via the web-based forms – unless such electronic entry is impossible. Print a copy of the completed USDA BSE Surveillance Submission Form, USDA BSE Surveillance Submission Continuation Form if used, and on each USDA BSE Surveillance Data Collection Form to accompany the samples shipped to the designated laboratory. If the BSE Surveillance Submission Form is submitted electronically, the submitter should keep a hard copy of the form and each BSE Surveillance Data Collection Form and retain those on-site.

- ☐ **Submit samples and corresponding paperwork to the designated laboratory for your location.** Refer to the list of designated laboratories in the attached table (see pages 21-22).

☐ **Collect all animal identification devices, brands (via digital picture or drawing), and tattoos (refrigerate tissue containing tattoo) from each animal sampled.** Bag these identification items, label them with the sample number and bar code sticker, attach a copy of the USDA BSE Surveillance Submission Form, and save until negative results are received. If samples are obtained for other disease programs (i.e., tuberculosis) from the same animal, record the animal identification on the appropriate submission form and indicate on the form where the identification items are stored. When whole carcasses are held, the ID may be stored on the carcass until results are returned. All parts of a stored carcass should be identified with an appropriate device.

☐ **Distribute and file copies of the completed sample forms.** Provide copies to the VS Area Office, the collection site, one set to be maintained with the identification devices, and one set for the sample submitter's file. Samples for which appropriate information is not recorded will not be counted towards the target. Samples from animals which do not meet the listed criteria will not be counted towards the target. These samples will be tested, but they will not contribute to the overall numbers.

☐ **Notify the designated laboratory of the incoming samples.**

☐ **Confirm with the overnight contract delivery service that the samples were delivered to the laboratory.**

☐ **Designated laboratories will report "not detected" or "inconclusive" screening test results back to the sample submitter, the AVIC, and when requested, to plant management of the facility where the sample was collected.** Rapid screening test results will be reported as either "not detected" or "inconclusive," in accordance with VS Memo 580.16 (Appendix A).

Personal Safety

If BSE is transmissible to humans in the occupational setting, the most likely routes would be through contact with infective tissues through wounds or open lesions on the skin, contact with mucous membranes (eyes and mouth), or exceptionally, by swallowing. Transmission by the airborne route (i.e., by the inhalation of infectious airborne particles) is considered to be the least likely route of exposure. In naturally BSE affected cattle, the only tissues that have shown infectivity are the brain, retina, and spinal cord. In experimentally (orally) affected cattle, the distal ileum has also shown infectivity.

Because rabies, listeriosis, and other possible zoonotic diseases must be included in the differential diagnosis, brain and spinal cord collection from cattle with CNS clinical signs should be done carefully. The following precautions are generally applicable:

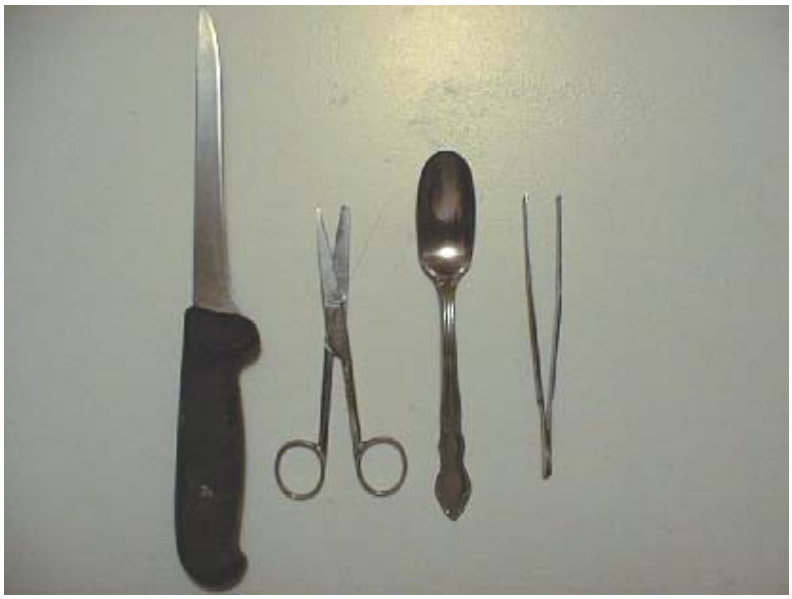
- Adhere to safe working practices and take extra precautions to avoid or minimize the use of tools and equipment likely to cause cuts, abrasions, or puncture wounds.
- Where use of such equipment is unavoidable, wear suitable protective clothing which includes disposable coveralls, aprons, heavy gloves and boots.
- Cover existing cuts, abrasions, and skin lesions on exposed skin with waterproof dressings.
- Use face protection such as a facemask and face shield or goggles to protect the mucous membranes of the eye, nose, and mouth from exposure to infective droplets or tissue fragments.
- Take steps to avoid the creation of aerosols and dusts when engaged in activities such as sawing through the skull bones.
- Wash hands and exposed skin before eating, drinking, smoking, taking medication, using the telephone, or going to the toilet.
- Wash and disinfect protective clothing and instruments thoroughly after use.

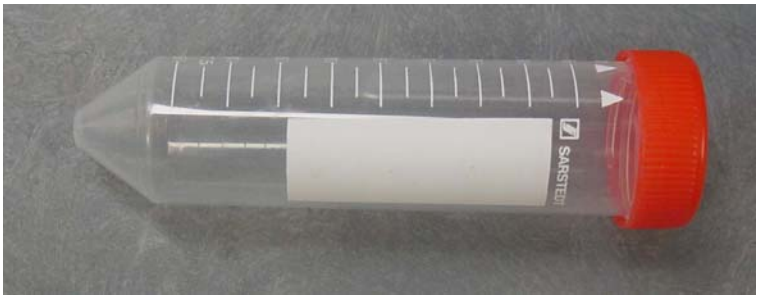
Detailed Sampling Procedures

These are the step-by-step procedures for sampling. For a one-page summary, see Appendix D.

Tools needed

- Knife and scissors
- Spoon (or other suitable device)
- Forceps
- Screw top plastic tubes (50ml)
- Fine point permanent marker
- Ball-point pen
- Pan or bucket for disinfecting instruments and rinsing gloved hands
- Bleach (disinfectant)
- Paper towels
- Trash bags
- Supply of BSE mailers (including frozen cold packs)
- May need scabbard, a steel and personal protective equipment





Getting a Sample of Sufficient Quality

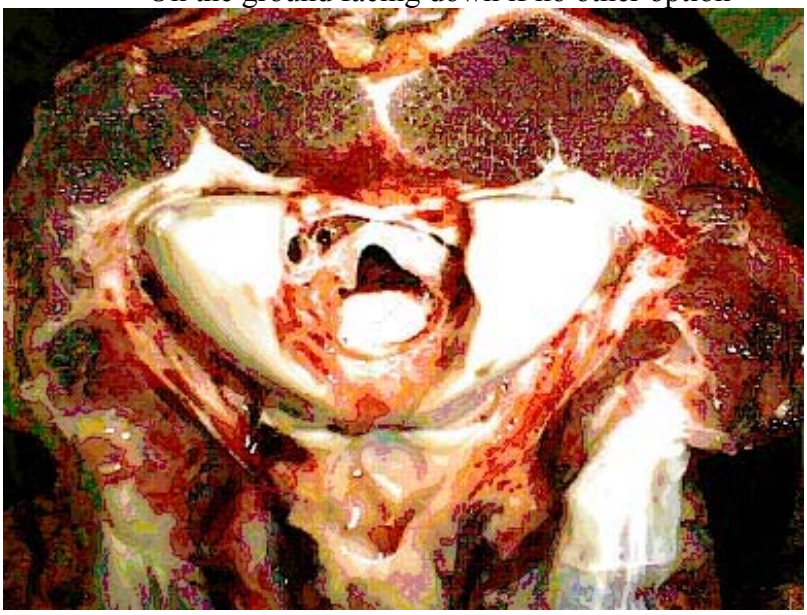
Unless the sample is of sufficient quality, it will be unusable and not count towards the survey. Please see Appendix E for guidance on collecting a quality sample. If the sample is not of sufficient quality, STOP: DO NOT TAKE THE SAMPLE. This does NOT apply to samples taken from:

- animals that are highly suspicious for BSE or that involve an FAD investigation
- animals that were condemned in an antemortem inspection

BSE sampling using a spoon

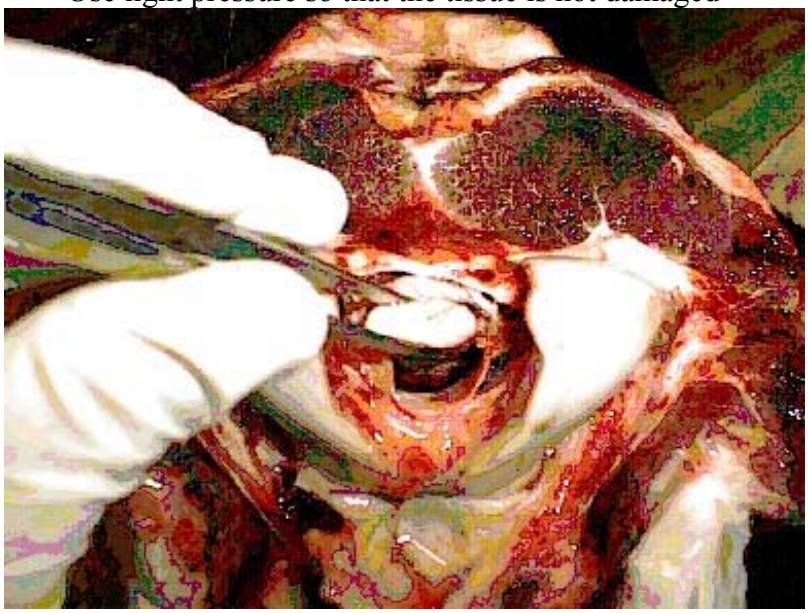
Step 1

- Place head upright
  - On head rack or barrel
  - On table edge
  - On the ground facing down if no other option



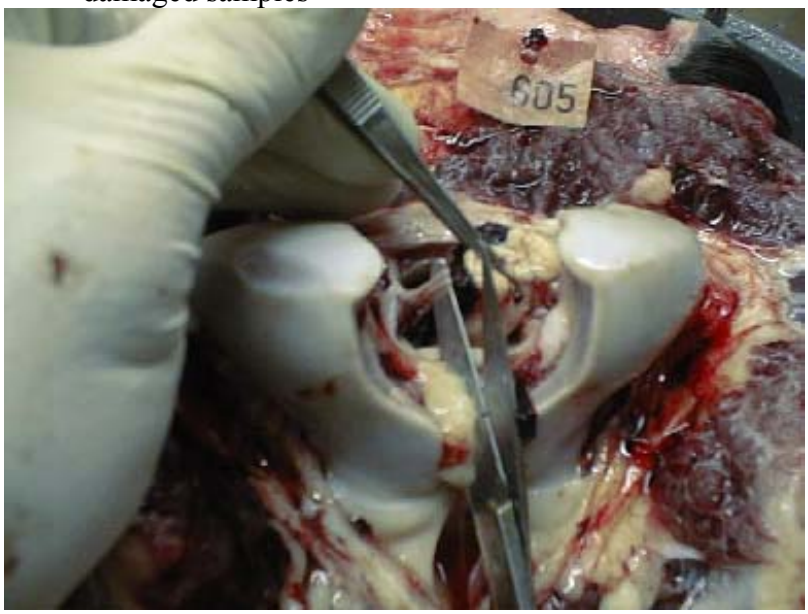
Step 2

- Grasp the spinal cord with forceps
- Use light pressure so that the tissue is not damaged



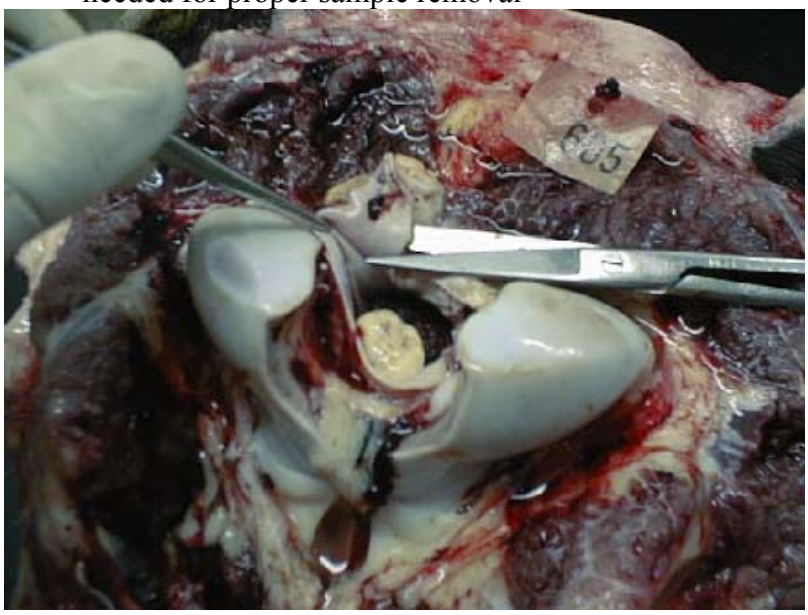
Step 3

- Cut the dura mater & cranial nerves
- Cut down each side of the spinal cord about ½" or more
- Cut on the sides – do not cut into the spinal cord
- Failure to sever cranial nerves is a common cause of damaged samples



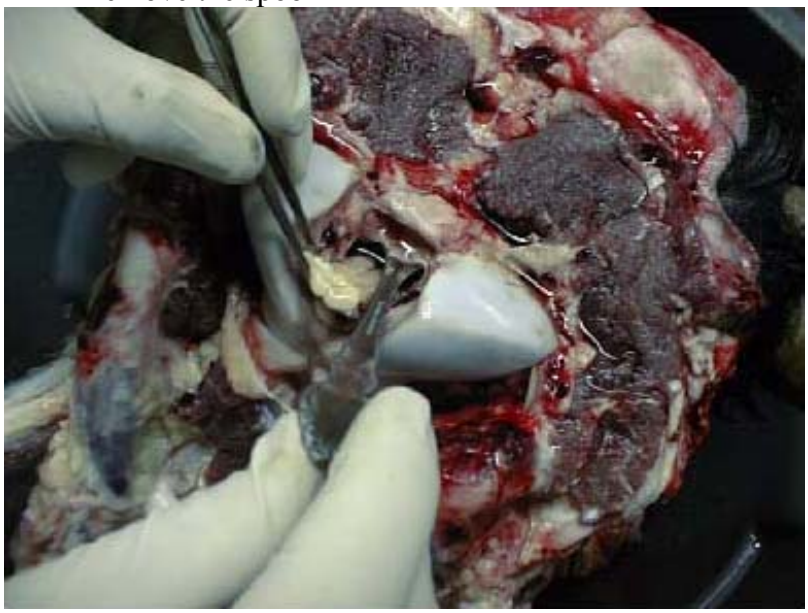
Step 4

- With forceps and scissors remove as much dura mater as possible
- Dura mater removal allows better visualization and is needed for proper sample removal



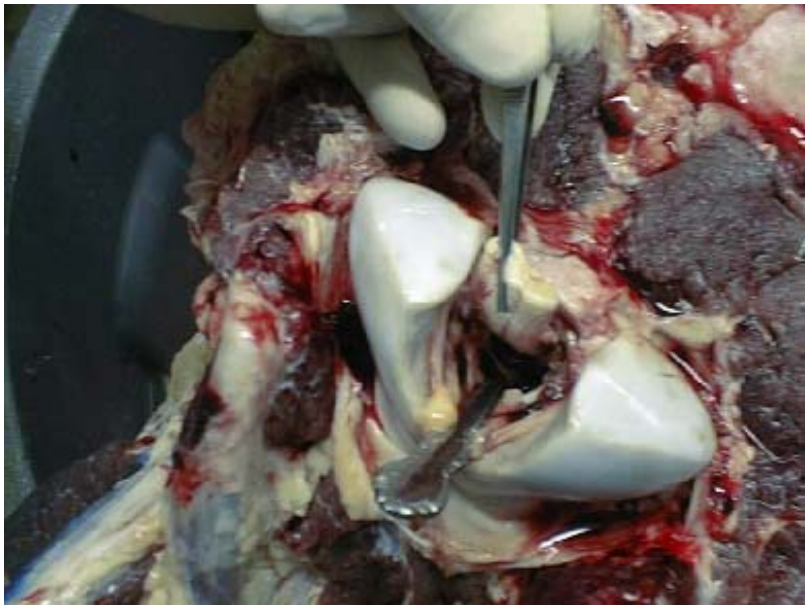
Step 5

- With light pressure use forceps to hold the spinal cord to the ventral part of the foramen
- Insert the spoon (inverted) on the dorsal part of the spinal cord to sever the cerebellum
- Remove the spoon



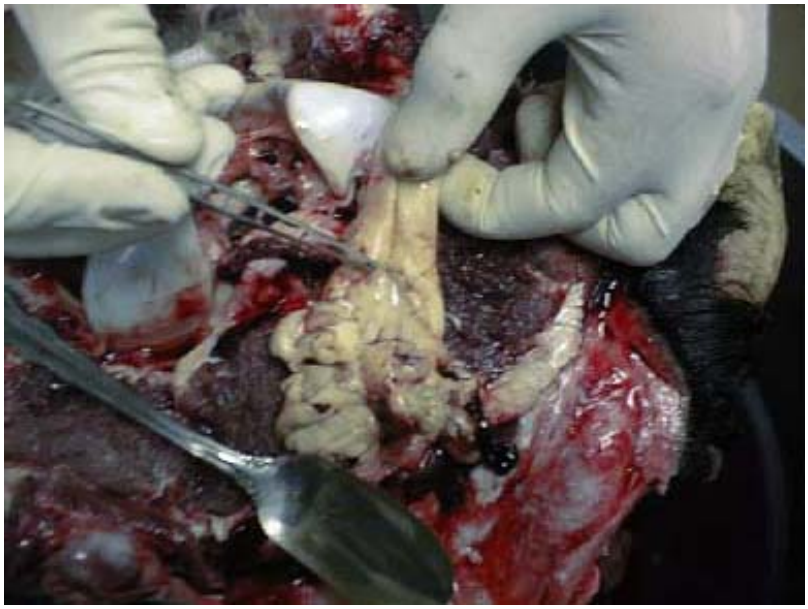
Step 6

- With forceps lift the spinal cord dorsally and re-insert along the ventral surface of the spinal cord
- Lower the handle of the spoon to sever the cord/brain stem
- With constant upward pressure/dorsal movement of the front edge of the spoon, gently work the severed sample from the foramen



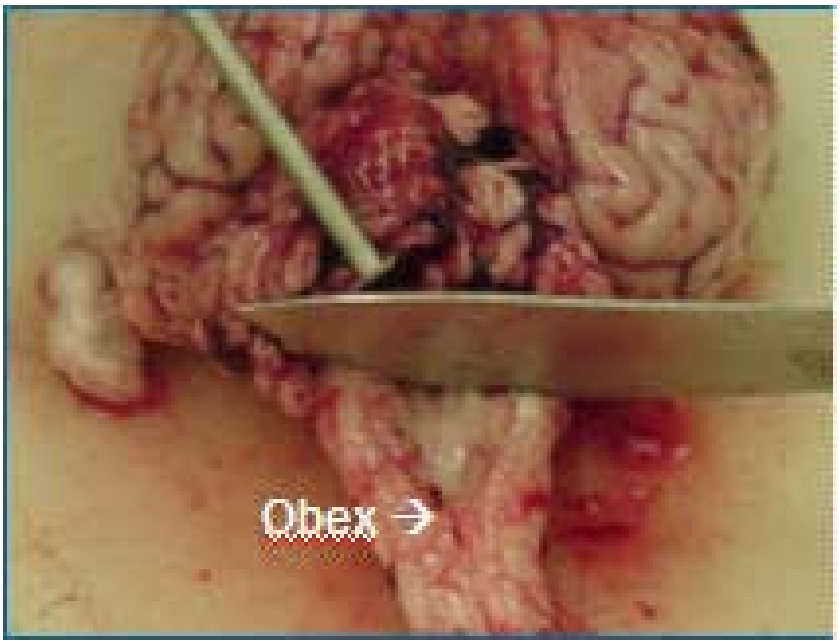
Step 7

- Complete removal of the sample from the foramen
- Clean off excess blood



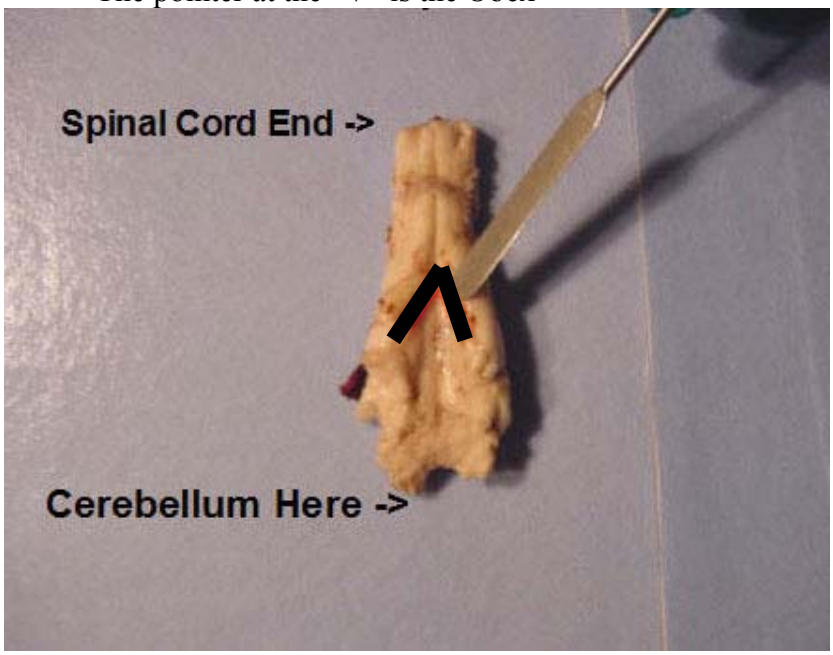
Step 8

- You should be able to identify the Obex area of the brain
- Make sure your samples contain the Obex
- The Obex **MUST** be collected for the sample to be used in BSE the surveillance data



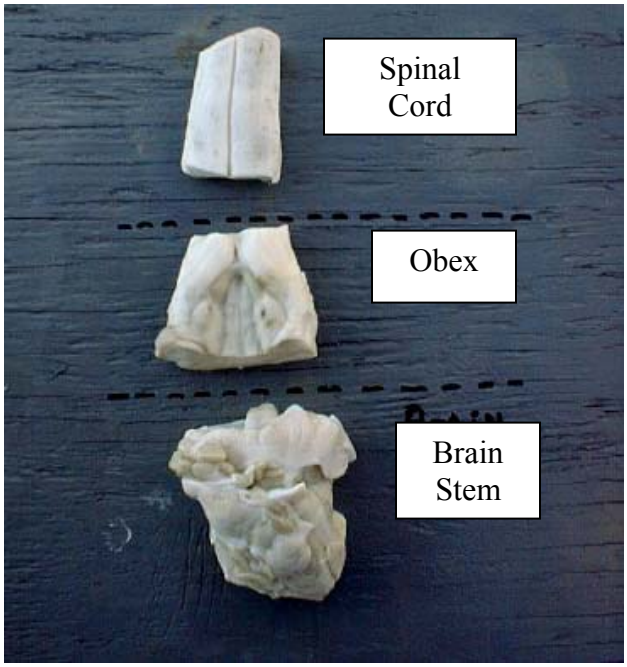
Note:

- The area marked in **black** is the location of the Motor Nucleus of the Vagus nerve
- The nucleus appears as "pink fleshy" areas
- This nucleus is the area we examine in the lab
- The pointer at the "V" is the Obex



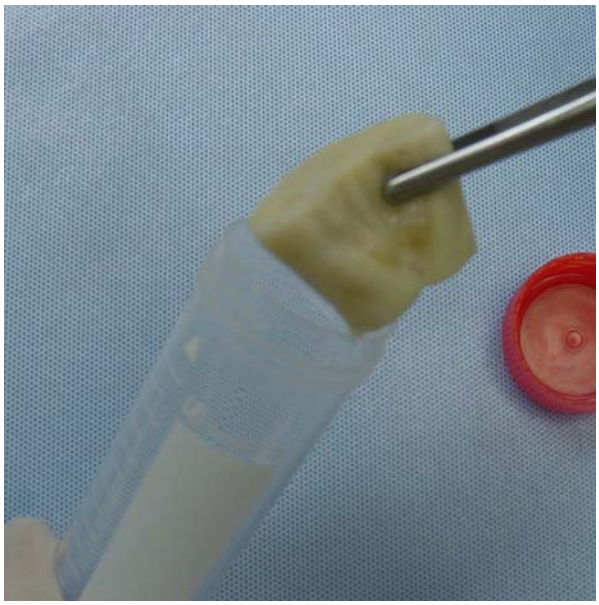
Step 9

- Cut the samples as pictured
- The middle piece of tissue contains the Obex and the Motor Nucleus of the Vagus
- The Obex is the **key area**



Step 10

- Remember the sample will be ***FRESH*** tissue
- **NO** formalin
- Place the Obex in the supplied screw top tube
- Label the sample tube with:
    - Sample number (ex: 1,2,3,4)
    - Barcode ID label
- Dispose of non-submitted tissue with carcass



Shipping the Sample

Packaging Materials (Supplied from NVSL as BSE Kits)

- Approved shipping box.
- Plastic bag or Zip-loc bag to place sample tubes in.
- USDA BSE Surveillance Submission Form.
- USDA BSE Surveillance Data Collection Form.
- Absorbent material.
- Ice packs.
- (2) bio-hazard bags (to comply with the International Air Transport Association (IATA) shipping regulations)
- Labels for shipping regulations compliance (air eligible, IATA statement, UN 3373, Keep from heat/freezing, Animal Diagnostic Specimen)

Packing and Shipping

- Fill out USDA BSE Surveillance Submission Form (attaching bar code label) and USDA BSE Surveillance Data Collection Form (attaching bar code label) (see Appendix G for guidance on completing forms).
- Place labeled sample tubes into plastic bag with absorbent.
- Place plastic bag into clear bio-hazard bag (STP-741) and seal.
- Place this bag into white bio-hazard bag (STP-740) and seal.
- Place the white bag into your shipping box.
- Place frozen ice packs on top of the bag.
- Place completed USDA BSE Surveillance Submission Form and USDA BSE Surveillance Data Collection Form on top of inner Styrofoam lid.
- Seal box
- Place address shipping label on the box (supplied by local Federal veterinarian); addressed to appropriate laboratory conducting BSE testing for your state.
- Place the other required shipping labels on the box.
- Ship by overnight delivery with the Federal contract service.
- If shipping on a Friday, be sure to mark/label box for Saturday delivery.

Place sample tube on cold packs as soon as possible.

Do NOT freeze!

Sample packed in sample tube.

NVSL supplies a certified shipping box and all supplies need for shipping as BSE kits. To request additional BSE kits, fax a request to number noted below.

Samples contained in formaldehyde are exempt from requirements for diagnostic specimens. Formalin fixed samples should be sent only to NVSL and returned in the box with the absorbent material provided by NVSL.

If you need further assistance with shipping, you may contact the shipping department at:

National Veterinary Services Laboratories
1800 Dayton Avenue
Ames, IA 50010
Ph: (515) 663-7530
Fax: (515) 663-7378

Designated Laboratories for BSE Sample Submission

NOTE: All highly suspicious cases as defined in VS Memo 580.16 must be sent to NVSL.

State where sample collected	Designated laboratory
Iowa, Illinois, Indiana, Hawaii, Alaska, Puerto Rico, Kentucky, Ohio, West Virginia, Minnesota	USDA, APHIS, VS, NVSL 1800 Dayton Ave. Ames, IA 50010 Steve Growen 888-273-6875 bsemailcases@aphis.usda.gov
Texas, Arkansas, Louisiana, New Mexico	Texas A&M University TVMDL Pathology Department 1 Sippel Road College Station, TX 77843 Dr. Levle Gayle 979-845-3414
Washington, Oregon, Idaho, Montana	Washington State University WADDL Animal Disease Diagnostic Laboratory Bustad Hall Room 155-N Pullman WA 99164-7034 Tim Bazzler 509-335-9696
Georgia, Mississippi, Alabama, Tennessee, Virginia, North Carolina, South Carolina, Oklahoma, Florida	Athens Diagnostic Laboratory College of Veterinary Medicine University of Georgia Athens, GA 30602 Doris Miller 706-542-5568
California, Arizona, Nevada	CAHFS-Thurman Bldg West Health Science Drive UC Davis Davis, CA 95616 Jackie Parker 530-753-6352
Colorado, Utah, Wyoming, Nebraska, South Dakota, North Dakota, Kansas, Missouri	Colorado State University Veterinary Diagnostic Laboratory 300 West Drake, Rm. E-100 Ft. Collins, CO 80526 Dr. Barbara Powers 970-297-1281

New York, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, Vermont, Rhode Island, Delaware, Connecticut, Michigan, Pennsylvania	Cornell University Animal Health Diagnostic Laboratory College of Veterinary Medicine at Cornell Upper Tower Road Ithaca, NY 14853 Edward J. Dubovi 607-253-3900 tselab@cornell.edu
Wisconsin	WVDL – TSE Laboratory 6101 Mineral Point Rd Madison, WI 53705 Dr. Phil Bochsler 608-262-5432

The following states will be sending samples to one of five additional laboratories when they are on-line. Notification will be sent out and this table will be changed as these labs come on-line.

- Florida
- Kansas
- Kentucky
- Minnesota
- Missouri
- Ohio
- Pennsylvania (central and eastern)
- West Virginia

Proper Communication for Submitting Samples

It is essential to have secure and reliable communication among the individuals responsible for sample collection at collection locations, establishments' management, and NVSL or designated laboratories. Sample submitter – designated laboratory communication guidelines are as follows:

- The sample submitter will notify the appropriate laboratory (see pages 20-21) of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method (unless otherwise instructed by that laboratory). This includes when electronic submission of the BSE Surveillance Submission Form is used. The information to be communicated will include the overnight contract delivery service tracking number, the collection site name and address, the unique Referral Number of the submission, and the number of samples. There is currently a dedicated e-mail box for notifying NVSL of incoming samples (bsemailcases@aphis.usda.gov). Sample submitters must accurately record all relevant information on the USDA BSE Surveillance Submission Form, USDA BSE Surveillance Submission Continuation Form if used, and on each of the USDA BSE Surveillance Data Collection Forms. Enter this information on the electronic version of these forms – either on a tablet PC or via the web-based forms – unless such electronic entry is impossible. Print a copy of the completed BSE Surveillance Submission Form, BSE Surveillance Submission Continuation Form if used, and on each BSE Surveillance Data Collection Form to accompany the samples shipped to the designated laboratory. Prepare four (4) copies of these completed forms for further distribution and filing (one for the submitter, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices). See Appendix G for instructions on completing the BSE Surveillance Submission Form and BSE Surveillance Data Collection Form. See Appendix H for instructions on using barcodes in shipping the sample.

- The paper version of the BSE Surveillance Submission Form has space to indicate the identification number for 20 animals. If additional animals are sampled, the sample submitter should submit a BSE Surveillance Submission Continuation Form listing the unique identification numbers for each additional animal.

- The sample submitter should verify, via the overnight contract delivery service tracking system, that the submission has been delivered to the designated laboratory. If the sample does not arrive as expected, the sample submitter should work with the delivery service to determine the location and delivery status of the sample.

Disposal

1. Disposal of carcasses and offal from sampled cattle – Dispose of carcasses and offal in compliance with Federal, State, and local laws. Acceptable options include the following, among others:
    - Refrigerate or freeze pending test results, then render or otherwise process after negative test results obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product).
    - Render at dedicated facilities, if available – render for non-animal feed use, such as biofuel or cement.
    - Bury in a landfill or on-the-farm.
    - Use alkaline digestion.
    - Incinerate.

2. Hides – Hides need not be disposed or held pending test results.

3. Sample disposal – Laboratories will dispose of samples using standard operating procedures.

July 13, 2004

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 580.16

SUBJECT: Procedures for investigations and surveillance of targeted cattle for bovine spongiform encephalopathy (BSE)

TO: Regional Directors, VS
Area Veterinarians In Charge (AVICs)

I. PURPOSE

Testing animals in the targeted populations as described in this memorandum comprises the national surveillance program for BSE, beginning in June 2004. The goal of the program is to test as many animals as possible in the described targeted high-risk population over a 12- to 18-month period. At the end of this period, the results will be evaluated and future policies will be adjusted as necessary depending on this evaluation.

The purpose of this memorandum is to clarify the procedures for:

- Foreign Animal Disease (FAD) investigations of adult cattle with clinical signs of BSE (highly suspicious for BSE);
- Sampling targeted high-risk cattle for BSE surveillance purposes (including cattle condemned on antemortem inspection); and
- Sampling limited numbers of apparently normal adult animals presented at slaughter.

II. CANCELLATION

Veterinary Services Memorandum No. 580.16, dated June 11, 1997, is hereby canceled.

III. FAD INVESTIGATIONS OF CATTLE HIGHLY SUSPICIOUS FOR BSE

Cattle exhibiting clinical signs as described below should be categorized as highly suspicious for BSE and should receive a complete FAD investigation as described in Veterinary Services Memorandum 580.4. Other animals that have abnormal central nervous system (CNS) clinical signs but do not fall into the highly suspicious for BSE category should be sampled within the established framework of the BSE Surveillance plan, and additional information on these animals should be captured in the supplemental data forms as attached.

There are no clinical signs that are pathognomonic for BSE. Animals that are highly suspicious for BSE may only display a few of the signs and signs may vary significantly in severity. True rabies suspects (*i.e.*, animals in areas where there is a significant level

of endemic wildlife rabies and where veterinary practitioners frequently encounter domestic animal exposures) should be treated as such and submitted for rabies testing prior to submission for BSE testing if they are negative for rabies.

The Office International des Epizooties Code (Appendix 3) has established a minimum number of annual investigations of cattle showing clinical signs consistent with BSE required for effective surveillance according to the total cattle population over 30 months of age. Assuming an adult cattle population of 45,000,000 for the United States, the minimum number under this guideline is approximately 450. Animals that meet the following description will be counted in this category.

The following are the criteria for identifying an animal that is highly suspicious for BSE.
Cattle of any age:

1. Affected by illnesses that are refractory to treatment, including but not limited to, anorexia; loss of condition in spite of a good appetite; pneumonia; and decreased milk yield AND that are displaying progressive behavioral changes, including but not limited to, apprehension; nervousness; excitability; aggression towards other cattle or humans; head shy with head held low; persistent kicking when milked; high stepping; difficulty in rising; excessive nose scratching; changes in herd hierarchical status; hesitation at doors, gates, and barriers; and reluctance to cross concrete or other "slippery" surfaces. Reports of progressive behavioral changes by a farmer or animal caretaker should be taken seriously even if the animal seems "normal" on investigation since in the early clinical stages of BSE these signs may be subtle and not easily noticeable by the investigating veterinarian.
2. Displaying progressive neurological signs that cannot be attributed to infectious illness and that are not responsive to treatment.

Sample collection and submission for cattle that are highly suspicious for BSE:
Cattle that show highly suspicious clinical signs should be observed over a period of time (at least 2 weeks) if possible, to determine whether the signs become progressively more severe. If at this time improvement or recovery has not taken place, the suspect animal should be humanely euthanized with an appropriate method and submitted for testing.

The following collection procedure will provide acceptable brain specimens for testing both for rabies and BSE. Submission of brain specimens for rabies testing will be left to the professional judgment of the Veterinary Medical Officer. Rabies testing should be done at the appropriate State or local public health department. Therefore, we recommend that you work with appropriate public health personnel (laboratory and epidemiology) in your State to discuss: (1) collection procedures that will provide acceptable brain specimens for testing for both rabies and BSE, (2) procedures for rabies sample submission, and (3) if rabies negative, maintenance and submission of fresh specimen quality for forwarding to the National Veterinary Services Laboratories (NVSL) for BSE testing.

The following collection procedure will provide acceptable brain specimens for testing both for rabies and BSE.

1. The entire brain should be removed intact with a portion of the cranial cervical spinal cord attached.
2. If rabies testing is required, the brain should be submitted intact to the local rabies laboratory for testing as required by the local laboratory for bilateral sampling. If appropriate and agreed upon in advance, the medulla can be removed at the level of the obex as described below. The obex and cranial cervical spinal cord can be submitted to NVSL for BSE sampling, and the remainder of the brain can be submitted to the rabies laboratory.
3. If rabies negative:
    a. The brain stem is transected at the level of the medulla (caudal to the cerebellar peduncles at cranial nerve 10) and at the junction of the medulla and spinal cord. This part of the brain stem containing the obex is placed in a screw top tube (if the carcass is retained and a fast turn around time is needed) or in a screw top bottle containing at least 200 ml of 10% neutral buffered formalin. The portion of the cranial cervical spinal cord (approximately 1/2 inch section) is placed in the plastic bag and frozen. This is the MINIMUM sample required for BSE testing and must be sent to NVSL.

    b. The reminder of the brain can be divided in half by cutting along the midline in the space between the cerebral hemispheres and continuing the midline cut through the cerebellum and the remainder of the caudal brain stem (pons and medulla). One of the cerebral hemispheres with attached midbrain should be placed in a whirl pack or plastic bag and frozen. The other half of the cerebrum with attached midbrain should be placed in a liter bottle of 10% neutral buffered formalin. The fixed samples are sent to NVSL, and the frozen samples should be held at the submitting laboratory until initial testing is completed.

Specimens should be shipped to NVSL, 1800 Dayton Road, Ames, Iowa, 50010, by Federal Express using procedures specified in Veterinary Services Memorandum No. 580.4, Procedures for Investigating a Suspected Foreign Animal Disease (FAD). The package must be marked for Saturday delivery if shipping via Federal Express on Friday.

IV. SAMPLING TARGETED HIGH-RISK CATTLE FOR SURVEILLANCE:

Animals in any of the following categories are to be included in the targeted surveillance efforts. Animals that are highly suspicious for BSE as outlined in the previous section should be treated as an FAD investigation, and follow procedures in Veterinary Services Memorandum No. 580.4. All other animals in the listed categories should be sampled as part of routine targeted surveillance. If there is a question about whether an animal should be sampled as part of routine targeted surveillance, take the sample, record the appropriate data, and submit the sample.

Definition – Targeted Cattle Population

Age – Unless otherwise designated, samples should only be obtained from animals over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors.

Clinical Presentation Criteria

1. Cattle that cannot rise from a recumbent position (downer) or that cannot walk including, but not limited to, those with broken appendages; severed tendons or ligaments; nerve paralysis; fractured vertebral columns; or metabolic conditions as well as cattle that are severely weakened though they may be able to stand and walk for brief periods of time.

2. CNS signs and/or rabies negative – sample animals of any age:
    a. Diagnostic laboratories – samples submitted due to evidence of CNS clinical signs.
    b. Public health laboratories – rabies negative cases.
    c. Slaughter facilities – CNS antemortem condemns at slaughter, sampled by the Food Safety and Inspection Service (FSIS).
    d. On-the-farm – CNS FAD investigations.

3. Cattle exhibiting other signs that may be associated with BSE – Cattle that were condemned or euthanized or that died as a result of a moribund condition, tetanus, emaciation, injuries, or non-ambulatory conditions.

4. Dead cattle – Any dead cattle where the specimen is of diagnostic quality and the cause of death and/or clinical signs prior to death, if known, do not preclude it from the targeted population.

Cattle condemned on antemortem inspection at slaughter:
Samples will be collected from all cattle condemned on antemortem inspection at both State and Federally inspected slaughter plants. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled. All cattle, with the exception of veal calves (less than 400 pounds at slaughter), condemned by FSIS upon antemortem inspection for any reason other than CNS will be sampled. This sampling will be done on-site at the slaughter establishment unless documentable, verifiable alternative arrangements for off-site sampling have been approved in advance. Sampling done on-site at the slaughter establishment will be done by FSIS personnel at Federally inspected plants, and either APHIS or State personnel at State inspected plants. Sampling done through approved off-site arrangements will be done by APHIS personnel or their contractors. Samples will be collected from these animals and submitted to the designated laboratory regardless of sample quality. Results from testing of cattle in this category will be provided; however, unless the samples are from cattle that meet the above definition of targeted samples, these data will not be included in the statistical analysis nor will they count toward our BSE surveillance sampling target.

Collection sites:
Samples can be collected most efficiently and cost-effectively at concentration points. These are facilities where multiple animals or carcasses are collected, such as a rendering facility, a deadstock collection point, or a salvage (3D/4D) slaughter facility. While focusing efforts on these facilities will allow the highest number of samples to be collected within a defined time frame, samples may be collected at any site where targeted animals are located. In addition to those previously identified, this may include on the farm, State or Federally inspected slaughter facilities, livestock markets, veterinary clinics, diagnostic laboratories, or any other facility as necessary.

V. RANDOM SAMPLES FROM APPARENTLY NORMAL ADULT ANIMALS PRESENTED FOR SLAUGHTER

A total of 20,000 samples will be obtained from randomly selected apparently normal adult animals presented for slaughter. These animals must be greater than 30 months of age. These samples will be obtained from animals presented for slaughter in a proportional allocation at the 40 largest adult slaughter facilities that slaughter the majority of adult cows and bulls.

The samples from these selected animals may be collected either at the selected slaughter facility or at an alternative site approved in advance. Any random selection tools – either for individual facilities or for combined facilities – must be approved in advance by APHIS' Veterinary Services (VS). Carcasses from sampled animals intended for human consumption must be held until negative test results are obtained as addressed in FSIS policies (FSIS Notice, published Jan 12, 2004, Docket No. 03-048N). Although there are no requirements to hold offal or other inedible products pending test results, APHIS can assist and facilitate such storage or disposal as necessary.

Results from testing of cattle in this category will be provided; however, these data will not be included in the statistical analysis.

VI. SAMPLING AND SUBMISSION PROCEDURES FOR TARGETED SURVEILLANCE SAMPLES AND APPARENTLY NORMAL SAMPLES

The brain stem, including the obex, will be collected using a brain tissue spoon or other acceptable device. Sampling spoons and tools will be provided by NVSL to sample collectors. Fresh tissue samples will be submitted to designated laboratories as listed in the attached table.

Sample collectors are responsible for evaluating the suitability of the tissue sample. Samples that are taken from the wrong location or that are significantly autolyzed are not testable, and should not be submitted unless specific arrangements are made in advance. See attached sheet for guidance on acceptable tissue samples.

Sample collectors are responsible for accurately recording all relevant information on VS Form 10-4 and the Supplemental Data Form. Data should be entered on the electronic version of these forms – either on a tablet PC or via the web-based forms – unless such electronic entry is impossible. Hard copies of these forms should be used only for the occasional submitter or when or where the electronic system is not working. VS Form 10-4 is submitted – either electronically or in hard copy – to the designated laboratory. When submitted electronically, a complete hard copy of VS Form 10-4 does not need to accompany the shipment. A summary sheet as required by shipping regulations will suffice to accompany the shipment.

All animal identification devices, brands (via digital picture or drawing), and tattoos (refrigerate tissue containing tattoo) will be collected from each animal sampled. These identification items will be bagged, labeled with the sample number, and then attached to a copy of VS Form 10-4 and saved by the sample collector until negative results are received. In certain instances, samples from other disease programs (tuberculosis, for example) may be obtained from the same animal, and identification devices are required to accompany those samples to the laboratory. Animal identification will be recorded appropriately on all submission forms in these instances, with appropriate notification as to where the identification devices are stored.

Samples for which appropriate information is not recorded or samples from animals that do not meet the criteria listed in this memorandum will not be counted towards the target. These samples will be tested, but they will not be counted towards our surveillance sampling target.

Routine surveillance samples should be sent to the appropriate designated laboratory, according to the State in which the sample was collected. Attachment 2 provides the list of designated laboratories and the States from which they will receive samples.

Designated laboratories will report rapid screening test results to the sample submitter, the AVIC, and when requested, to plant management of the facility where the sample was collected. Rapid screening test results will be reported as either negative or inconclusive. In accordance with agreed laboratory standard operating procedures, any samples with inconclusive rapid screening test results must be immediately forwarded to NVSL for confirmatory testing.

VII. COST RECOVERY PAYMENTS

Payments for the following services may be made according to approved cost recovery guidelines and payment procedures. Additional payments may be approved on a case-by-case basis with appropriate justification provided to and approved by the Regional Office.

Refer to the Animal Health Protection Act, agreement guidance, or Federal acquisition regulations for further specific payment information.

1. Transport, including the transport of an animal or carcass to the collection site from a farm, slaughter establishment, etc., and transport from the collection site to a storage, disposal, or rendering site. Payment would be based on per loaded mile fee (for dead or live animal). In addition, appropriate local agreements with renderers or deadstock haulers can be established when routine transport requirements can be predicted.

2. Disposal for all screening test inconclusive cattle and for other sampled cattle when rendering is not an option or when the cost of transport and storage at the renderer exceeds disposal costs. This may include the cost of disposal in a landfill, equipment for on-farm burial, incineration, or alkaline digestion.

3. Storage pending test results:
    a. Cold storage as needed to maintain carcasses in acceptable condition for rendering or other processing pending test results. Storage costs may be paid per day at any facility that does not have pre-existing cold storage facilities or that has limited storage where sampled cattle carcasses or parts are held pending test results or disposal.
    b. Alternatively, a facility may choose to allow rendering to occur and hold the final product pending negative test results. In the event of a positive diagnosis, the batch and an appropriate amount of "flush" material will be purchased and disposed of rather than paying for storage of raw materials. This option may be offered to facilities that have adequate storage capacity or allow storage facilities to be built, but will require a prorated price for the product.

4. Fee-basis payments for accredited veterinarians assisting with sample collection. These payments can be made in accordance with the intent of VS Memorandum No. 534.2 and the cost recovery guidelines.

5. Sample collection. Individuals located at collection sites may be used on a per sample basis for collecting appropriate tissue samples from the targeted population. Compensation will only be provided when samples meet the criteria in this memorandum and are counted toward the targeted goal.

VIII. COMMUNICATION AND REPORTING OF TEST RESULTS

It is essential to have secure and reliable communication among individuals responsible for sample collection at collection locations, establishment managements, and NVSL or designated laboratories. The following communication guidelines will be followed:

1. Sample collector – designated laboratory communication:
   - The sample collector will notify the appropriate laboratory of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method. This notification should occur even when an electronic VS Form 10-4 submission occurs. The information to be communicated will include the overnight contract delivery service tracking number, the collection site name and address, the unique submission reference number, and the number of samples. There is currently a dedicated e-mail box for notifying NVSL of incoming samples.
   - The sample collector will submit – either electronically or by hard copy - the original VS Form 10-4 and a Supplemental Data Form for each animal sampled with the samples sent to the designated laboratory. The collector will also make and distribute four copies of VS Form 10-4 (one for the collector, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices).
   - VS Form 10-4 has space to indicate the identification number for 10 animals. If additional animals are sampled, the sample collector should submit a continuation form listing the unique identification numbers for each animal. (Use VS Form 10-4A).
   - It is the responsibility of the sample collector to verify, via the overnight contract delivery service tracking system, that the submission has been delivered to the designated laboratory. If the sample does not arrive as expected, it is the responsibility of the sample collector to work with the delivery service to determine the location and delivery status of the sample. Samples not acceptable for testing will not be eligible for payment.

2. Communication from NVSL or designated laboratory:
   - The day the tests are completed, the designated laboratory will transmit a copy of the test results to the collector, the VS Area Office, and appropriate management at the collection site when requested. It is the responsibility of the collector to provide all necessary contact information on VS Form 10-4.
   - If all animals tested in the lot are rapid screening test negative, the designated laboratory will report results to the collector and, when requested, to the collection site. If any of the animals in the lot are screening test inconclusive, the designated laboratory report will be sent to the AVIC and will specify which carcasses tested inconclusive. The AVIC will notify the collection site, at the direction of the Deputy Administrator's office, in accordance with the policy on daily announcements of inconclusive results. A decision to hold or dispose of the carcasses pending confirmatory testing should be made with the concurrence of the AVIC.

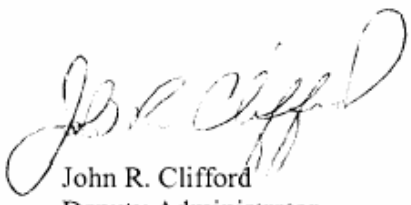
- Samples from all screening test inconclusives must be immediately forwarded to NVSL, with prior notification and confirmation of arrival. These should be sent via Federal Express or other appropriate method for overnight delivery in boxes or containers that have a security seal and in a manner that maintains chain of custody. NVSL confirmatory testing will include repeat screening tests and any other testing deemed necessary. All confirmatory test results will be transmitted directly to the VS Area Office so that carcass disposal can be coordinated and verified. The AVIC will contact the sample collector and the facility where the sample was collected.

IX. DISPOSAL

1. Disposal of carcasses and offal from screening test inconclusive or test positive animals – When necessary, disposal of carcasses and offal will be in compliance with Federal, State, and local laws. Acceptable options may include any of the following, among others:
   - Refrigerate or freeze pending test results, then render or otherwise process after negative test results are obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product).
   - Disposal by rendering at dedicated facilities, if available – rendering for non-animal feed use, such as biofuel or cement.
   - Burial in a landfill or on-the-farm.
   - Alkaline digestion.
   - Incineration.

2. Hides – Hides need not be disposed or held pending test results.

3. Sample disposal – Laboratories will dispose of samples using standard operating procedures.



John R. Clifford
Deputy Administrator
Veterinary Services

Attachment 1 – Personal safety

If BSE is transmissible to humans in the occupational setting, the most likely routes would be through contact with infective tissues through wounds or open lesions on the skin, contact with mucous membranes (eyes and mouth), or exceptionally, by swallowing. Transmission by the airborne route (*i.e.*, by the inhalation of infectious airborne particles) is considered to be the least likely route of exposure. In naturally BSE affected cattle, the only tissues that have shown infectivity are the brain, retina, and spinal cord. In experimentally (orally) affected cattle, the distal ileum has also shown infectivity.

Because rabies, listeriosis, and other possible zoonotic diseases must be included in the differential diagnosis, brain and spinal cord collection from cattle with central nervous system (CNS) clinical signs should be done carefully. The following precautions are generally applicable:

* Adhere to safe working practices and take extra precautions to avoid or minimize the use of tools and equipment likely to cause cuts, abrasions, or puncture wounds.
* Where use of such equipment is unavoidable, wear suitable protective clothing which includes disposable coveralls, aprons, heavy gloves and boots.
* Cover existing cuts, abrasions, and skin lesions on exposed skin with waterproof dressings.
* Use face protection such as a facemask and face shield or goggles to protect the mucous membranes of the eye, nose, and mouth from exposure to infective droplets or tissue fragments.
* Take steps to avoid the creation of aerosols and dusts when engaged in activities such as sawing through the skull bones.
* Wash hands and exposed skin before eating, drinking, smoking, taking medication, using the telephone, or going to the toilet.
* Wash and disinfect protective clothing and instruments thoroughly after use.

Attachment 2 – Designated laboratories

Designated laboratory	State in which sample collected
California Animal Health and Food Safety Lab System University of California ; Davis, CA	California, Arizona, Nevada
Colorado State University Veterinary Diagnostic Lab; Ft. Collins, CO	Colorado, Utah, Wyoming, Nebraska, South Dakota, North Dakota
Texas Veterinary Medical Diagnostic Laboratory; College Station, TX	Texas, Arkansas, Louisiana, New Mexico
Wisconsin Animal Health Laboratory; Madison, WI	Wisconsin
Washington State University Animal Disease Diagnostic Lab; Pullman, WA	Washington, Oregon, Idaho, Montana
Athens Diagnostic Laboratory, College of Veterinary Medicine University of Georgia; Athens, GA	Georgia, Mississippi, Alabama, Tennessee, Virginia, North Carolina, South Carolina, Oklahoma
NY State College of Veterinary Medicine Veterinary Diagnostic Laboratory, Cornell University; Ithaca, NY	New York, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, Vermont, Rhode Island, Delaware, Connecticut, Michigan, *Pennsylvania (western Pennsylvania only)
USDA, APHIS, National Veterinary Services Laboratory (NVSL); Ames, IA	Iowa, Illinois, Indiana, Hawaii, Alaska, Puerto Rico
Kissimee Diagnostic Laboratory, Florida Dept of Agriculture and Consumer Services; Kissimee, FL	Florida
Minnesota Veterinary Diagnostic Laboratory University of Minnesota; St. Paul, MN	Minnesota
Veterinary Diagnostic Laboratory Kansas State University; Manhattan, KS	Kansas, Missouri
U.S.Department of Agriculture Laboratory; Frankfort, KY	Kentucky, Ohio, West Virginia
Pennsylvania Veterinary Laboratory; Harrisburg, PA	Pennsylvania (central and eastern Pennsylvania)

Note: The following is included as a reference document for historical purposes; some aspects of this document are no longer applicable.

* * *

Bovine Spongiform Encephalopathy (BSE) Surveillance Plan
March 15, 2004
(Updated with Additional Antemortem Condemnation Sampling Announced May 21, 2004)

The Animal and Plant Health Inspection Service (APHIS), in cooperation with the Food Safety and Inspection Service (FSIS), and the Food and Drug Administration (FDA), has developed an outline for an intensive national BSE surveillance plan. This one-time effort will give a snapshot of the cattle population in the US and help to define whether BSE is actually present in the population and if so, at what level. The goal of this plan is to test as many cattle in the targeted high-risk population as possible in a 12-18 month period. We will immediately initiate actions to ramp up our system and expect to reach full capacity in a 2-3 month period. We will analyze the results obtained over this period and evaluate future actions based on the results of this effort. This plan also discusses the incorporation of random sampling of clinically normal aged animals at slaughter in addition to the defined targeted surveillance goal.

A. Targeted High-Risk Population Sampling Plan

Surveillance Objective

Experience in the United Kingdom and Europe has shown that testing cattle that are non-ambulatory, dead on the farm, or showing clinical signs consistent with BSE is the method most likely to disclose BSE if it is present in the cattle population. Targeted surveillance efforts in recent years were designed to detect BSE in the adult cattle population at the level of at least one infected animal per million adult cattle with a 95 percent confidence level. The intensive one-time surveillance effort will allow us to determine more accurately whether BSE is present in the US cattle population, and if so, estimate the level of disease. By expanding our surveillance, we will be able to provide consumers, trading partners, and industry increased assurances about the BSE status of the U.S. cattle population.

The objective for this portion of the plan is to collect samples from as many adult cattle from the high-risk population as possible in 12-18 months while ensuring that there is statistically appropriate geographical representation of the adult cattle population in the United States. Assuming all the BSE positive cattle are part of the high risk population, if a total of 201,000 samples is collected, this level of sampling would allow us to detect BSE at the rate of 1 positive in 10 million adult cattle at a 95 percent confidence level. If a total of at least 268,500 samples is collected, this level of sampling would allow us to detect BSE at the same rate at a 99 percent confidence level.

High-Risk Population Estimates

The segment of the adult cattle population in which one is most likely to detect BSE if it is present is the population that contains animals that are exhibiting clinical signs consistent with BSE. The BSE disease takes years to develop from exposure to clinical signs, so that only older

animals are an appropriate population for BSE surveillance testing. Therefore, the high-risk population for testing includes adult cattle showing clinical signs involving the central nervous system (CNS), and dead and non-ambulatory cattle where clinical signs cannot be adequately evaluated. Based on currently available data, we estimate this population to be approximately 446,000 cattle. This estimate includes adult cattle in the following categories: condemned at slaughter for CNS signs; moribund; dead; injured or emaciated (FSIS data 2002); CNS abnormalities reported for foreign animal disease (FAD) investigations (APHIS data); died on farm for unknown causes; lameness, or injury that resulted in euthanasia; and cattle that died with signs of incoordination or severe depression (National Animal Health Monitoring System (NAHMS) data described below).

NAHMS conducts periodic surveys of livestock and poultry producers across the United States to characterize the health and management of animals. In 1997, NAHMS focused on breeding beef cattle. Overall, producers reported approximately 1.5 percent of adult cattle died annually. These death losses were attributed by producers to a variety of causes including digestive, respiratory, weather, and calving related problems as well as other known causes of death and death from unknown causes. Similarly, in 2002, NAHMS collected data to estimate that 4.8 percent of adult dairy cows die annually. Again, losses were attributed to various categories. Our calculations result in an estimate of 251,500 adult cattle that die on farm each year due to unknown reasons or reasons that could be consistent with BSE-related clinical signs. Estimates of the other described populations are 194,200 in the FSIS condemnation categories outlined, and a total of 129 reported FAD investigations of CNS abnormalities. These give a total of approximately 446,000 adult cattle estimated in the targeted high-risk population.

To ensure that the samples collected for BSE surveillance were geographically representative, these overall numbers were applied to the total cow population estimates (beef and dairy) of the United States as well as the individual State inventory of beef and dairy cows from the National Agricultural Statistics Service (NASS).

State-level data will be recorded based on the origin of animals from which samples are collected. The State in which a sample is collected is not necessarily the same as the State and premises of origin and other relevant data of the animal. Every effort will be made to accurately record the State of origin of animals in this targeted high-risk surveillance and other data. Assuming that most of these animals will not be moved significant distances (that is, most rendering or salvage facilities collect animals from a limited geographical area), information about the State of origin should be readily available.

Definition – Targeted Cattle Population
Age – Over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors.

Clinical Presentation Criteria
1. Non-ambulatory cattle, to include:
    a. Cattle that cannot rise from a recumbent position (downer) or that cannot walk including, but not limited to, those with broken appendages, severed tendons or

ligaments, nerve paralysis, fractured vertebral columns, or metabolic conditions; and

b. Cattle that are severely weakened though they may be able to stand and walk for brief periods of time.

2. CNS signs and/or rabies negative:*
    a. Diagnostic laboratories – samples submitted due to evidence of CNS clinical signs.
    b. Public health laboratories – rabies negative cases.
    c. Slaughter facilities – CNS antemortem condemns at slaughter.
    d. On-the-farm – CNS FAD investigations.

3. Cattle exhibiting other signs that may be associated with BSE – Cattle that were condemned or euthanized or that died as a result of a moribund condition, tetanus, emaciation, injuries, or non-ambulatory conditions.

4. Dead cattle – Any dead cattle where the specimen is of diagnostic quality and the cause of death and/or clinical signs prior to death, if known, do not preclude it from the targeted population.

Cattle Condemned on Antemortem Inspection at Slaughter

Samples will be collected from all cattle condemned on ante-mortem inspection at both state and federally inspected slaughter plants. All cattle, regardless of age, condemned by FSIS upon antemortem inspection for CNS impairment will be sampled. All cattle, with the exception of veal calves (less than 400 pounds at slaughter), condemned by FSIS upon antemortem inspection for any reason other than CNS will be sampled. This sampling will be done on-site at the slaughter establishment unless documented, verifiable alternative arrangements for off-site sampling have been approved in advance. Sampling done on-site at the slaughter establishment will be done by FSIS personnel at federally inspected plants, and either APHIS or state personnel at state inspected plants. Sampling done through approved off-site arrangements will be done by APHIS personnel or their contractors. Samples will be collected from these animals and submitted to the designated laboratory regardless of sample quality. Results from testing of cattle in this category will be provided; however, unless the samples are from cattle that meet the above definition of targeted samples, these data will not be included in the statistical analysis nor will they count toward our BSE surveillance sampling target.

Laboratory Capacity and Testing of Samples for BSE from Targeted Cattle

Testing of the targeted high-risk population samples will be conducted at APHIS' National Veterinary Services Laboratories (NVSL) and at participating network laboratories on a fee-for-service basis. High-throughput equipment (such as robotics systems) will be purchased for a limited number of laboratories to support this surveillance effort. As surveillance expands, the number of laboratories approved (if additional laboratories wish to participate) could be significantly larger. It is estimated that between 250,000-400,000 samples could be tested during a one year collection period, which could generate up to 2,000 samples on peak sampling days.

* Test all, regardless of age.

State veterinary diagnostic laboratories will be contacted to determine if they wish to participate in this program. Initially, these laboratories will be contacted based on the following points:

a. High targeted total sample allocation in their State.
b. Presence of chronic wasting disease (CWD) in the wildlife of the State (future use of technique and equipment).
c. Current contract for CWD/scrapie testing.
d. Geographic distribution.

Depending on the willingness of individual laboratories to participate in this program, a network of laboratories will be established throughout the continental United States.

An appropriate rapid screening test will be used to test time- critical samples. Some can be automated to run between 800-1000 samples per day. Samples that test positive by the rapid screening test will not be considered presumptive-positives; they will be classified as "suspects." The rapid screening test suspect samples will be tested by immunohistochemistry (IHC) and/or western blot at NVSL for confirmation.

A certain number of routine samples will be tested at NVSL as to ensure proficiency in conducting all licensed tests. Moreover, the use of network laboratories will allow NVSL to conduct quality assurance check-testing and to conduct confirmatory IHC testing of any suspects in a timely manner. Appropriate geographical distribution of network laboratories will ensure that a consistent and sufficient level of samples will be analyzed to optimize efficiency and competency.

Sample Collection for Targeted Cattle
The following procedures will be followed in sample collection:

1. Sampling – Sampling will be done by authorized State or Federal animal health or public health personnel, accredited veterinarians, or trained State or APHIS contractors.

2. Training – NVSL will train current collectors in the method of sample collection for use in rapid screening tests. APHIS or State personnel that have received training from NVSL will train additional sample collectors. Available training materials, including videos, CDs, and manuals, will be provided.

3. Quality assurance – NVSL will provide feedback to the Veterinary Services (VS) Area Offices regarding sample and data quality. If deficiencies are reported, VS Area Offices will ensure that corrective action is taken regarding sample and record quality.

4. Collection sites – Samples will be collected at any of the following sites as necessary:
    a. State or Federally inspected slaughter establishments.
    b. Custom exempt slaughter establishments.
    c. On-the-farm.
    d. Rendering facilities.
    e. Veterinary diagnostic laboratories.
    f. Animal feed slaughter facilities, i.e. pet food plants.

g. Public health laboratories – Rabies negative cases.
h. Veterinary clinics or other sites that accredited veterinarians might utilize.
i. Sale barns, livestock auctions, etc.

5. Site identification:
    a. FSIS will supply a list of State or Federally inspected slaughter establishments where sampling may occur.
    b. FDA will provide APHIS a list of renderers and other FDA regulated facilities receiving intact whole cattle carcasses.
    c. The Centers for Disease Control and Prevention will provide a list of public health laboratories that conduct rabies testing on cattle.
    d. NVSL will provide a list of veterinary diagnostic laboratories that provide diagnostic services for cattle.
    e. APHIS will enhance existing educational materials and processes to encourage reporting of suspect cattle identified on farm and for collecting samples from them. See Appendix A for an overview of educational and outreach activities.
    f. VS Area Offices will work to identify other potential collection sites within their areas such as veterinary clinics, dead stock handlers, and custom exempt slaughter facilities.

6. The VS Area Veterinarian in Charge (AVIC), who will work closely with the State Veterinarian and other officials as appropriate (such as the head of the State meat inspection program, public health veterinarians, and State environmental authorities), will establish a relationship with each site identified in "5" above, in his or her area, to facilitate the submission of samples from high-risk categories of cattle.

7. Safety – APHIS (and FSIS where needed) will provide the necessary safety equipment such as gloves, protective clothing, face masks, eye protection, etc., to their respective personnel or contractors for use during sample collection.

8. Sampling supplies – NVSL will provide supplies including scissors, spoons, forceps, screw top plastic tubes (50 ml), shipping boxes/containers, bags, VS Form 10-4 or equivalent submittal forms, cool packs, shipping labels, absorbent materials, and any other necessary items as required.

9. Data collection – The Sample Data Form and VS Form10-4 must be accurately completed.

10. Sample – The brain stem, including the obex, will be collected using a brain tissue spoon or other acceptable device. Samples must be appropriately identified and all animal identification devices will be collected from each animal sampled, as described in the next section.

11. Shipping – Means of shipping will be by overnight contract delivery service or by hand delivery if applicable. Samples will be maintained on cool packs and packaged according to current NVSL protocol.

Data collection and sample identification
All animal identification devices, brands (via digital picture or drawing), and tattoos (refrigerate tissue containing tattoo) will be collected from each animal sampled. These identification items will be bagged, labeled with the sample number, and then attached to a copy of the VS Form 10-4 and saved by the sample collector until negative results are received. In certain instances, samples from other disease programs (tuberculosis, for example) may be obtained from the same animal. Animal identification will be recorded appropriately on all submission forms in these instances, with appropriate notification as to where the identification items are stored.

The Sample Data Form and the VS Form 10-4 must be accurately completed and accompany the sample. Samples that are not accompanied by the appropriate submission forms with all necessary information will not be tested. NVSL or the network laboratory will notify the VS Area Office if there are problems with sample and/or data quality. VS Area Offices will ensure that corrective action is taken regarding sample and data quality if deficiencies are reported.

Cost Recovery and Participation
Payments for the following services would help cover additional costs incurred by industries participating in our surveillance; other payments would help encourage reporting and collection of targeted samples. All of these will be required to some degree in the attempt to collect samples from all of the targeted high-risk population.

1. Transport, including the transport of an animal or carcass to the collection site from a farm, slaughter establishment, etc., and transport from the collection site to a storage, disposal, or rendering site. Payment would be based on per loaded mile fee (for dead or live animal). In addition, contracts with renderers or deadstock haulers could be established when routine transport requirements could be predicted.

2. Disposal for all screening test suspect (non-negative) cattle and for other sampled cattle when rendering is not an option or when the cost of transport and storage at the renderer exceeds disposal costs. This may include the cost of disposal in a landfill, equipment for on-farm burial, incineration, or alkaline digestion.

3. Cold storage will be needed to maintain carcasses in acceptable condition for rendering pending test results. Storage costs may be paid per day at any facility that does not have pre-existing cold storage facilities or that has limited storage where sampled cattle carcasses or parts are held pending test results or disposal (36-48 hours in most cases).

4. Allow rendering to occur and require final products to be held pending negative test results. In the event of a positive diagnosis, the batch and an appropriate amount of “flush” material will be purchased and disposed of rather than paying for storage of raw materials. This option could be offered to facilities that have adequate storage capacity or allow storage facilities to be built, but would require a prorated price for the product.

Collection Methods and Sites
Samples can be collected most efficiently and cost-effectively at concentration points. These are facilities where multiple animals or carcasses are collected, such as a rendering facility, a

landfill, or a salvage (3D/4D) slaughter facility. Focusing efforts on these facilities will allow the highest number of samples to be collected within a defined time frame. Although samples will be collected on farms and from individual animals, additional samples will be necessary for this surveillance program.

If Federal or State employees collect samples, no fee will be paid to the collection site owner for collection of the sample. If another entity (such as a contractor, diagnostic laboratory, accredited veterinarian, or plant employee) collects samples, a fee may be paid per sample. Compensation would only be provided when sampling criteria have been met for the targeted cattle population

Collection sites: Samples may be collected at any of the following sites:

Location	**Animal Presentation**	**Personnel who may collect samples**
State or Federally inspected slaughter establishments	Ante-mortem condemns (includes non-ambulatory and CNS signs)	Federal or State employee, contractor, or accredited veterinarian
Custom exempt slaughter	Antemortem condemns (includes non-ambulatory and CNS signs)	Federal or State employee, contractor, or accredited veterinarian
On farm	Non-ambulatory and deadstock	Federal or State employee, accredited veterinarian, non-accredited veterinarian
On farm	CNS signs/suspect cases	Federal or State employee or accredited veterinarian
Rendering facilities (includes 3D/4D)	Non-ambulatory	Federal or State employee, accredited veterinarian, contractor, or plant employee
Rendering facilities (includes 3D/4D)	Dead stock	Federal or State employee, accredited veterinarian, contractor, or plant employee
Veterinary diagnostic laboratories	CNS signs/ non-ambulatory/ dead stock	Federal or State employee, diagnostic lab employee, or accredited veterinarian
Public health laboratories	Rabies-negative cases	Sample forwarded directly from laboratory
Veterinary clinics or other sites that accredited vets may use	CNS signs/ non-ambulatory/ dead stock	Federal or State employee or accredited veterinarian

BSE Sampling Communication Plan

It is essential to have secure and reliable communication among the individuals responsible for sample collection at collection locations, establishment managements, and NVSL or designated laboratories. The following communication guidelines will be followed:

1. For those infrequent sample collections at slaughter plants or for those animals condemned at slaughter, the FSIS Inspector in Charge and the sample collector will establish a working relationship with the plant manager to facilitate sample collection and/or the required data collection and animal identification needed to allow collection at another site.

2. Sample collector – designated laboratory communication:
    - The sample collector will notify the appropriate laboratory of incoming samples via facsimile, telephone, e-mail, or any other approved electronic method. A toll-free telephone number, with voicemail capability, will be established at each laboratory to facilitate this communication. The facsimile number should also be toll-free. The information to be communicated will include the overnight contract delivery service tracking number as applicable, the collection site name and address, the unique submission reference number, and the number of samples. There is currently a dedicated e-mail box for notifying NVSL of incoming samples.
    - The sample collector will include the original VS Form 10-4 and a Sample Data Form for each animal sampled with the samples sent to the designated laboratory. The collector will also make and distribute four copies of the VS Form 10-4 (one for the collector, one for the collection site, one for the VS Area Office, and one to be maintained with the identification devices).
    - The VS Form 10-4 has space to indicate the identification number for 10 animals. If additional animals are sampled, the sample collector should submit a supplemental form listing the unique identification numbers for each animal. (Use VS Form 10-4A).
    - It is the responsibility of the sample collector to verify, via the overnight contract delivery service tracking system, that the submission has been delivered to the designated laboratory. If the sample does not arrive as expected, it is the responsibility of the sample collector to work with the delivery service to determine the location and delivery status of the sample. Samples not acceptable for testing will not be eligible for payment.

3. Communication from NVSL or designated laboratory:
    - The day the tests are completed, the designated laboratory will transmit a copy of the test results to the collector, the VS Area Office, and the management at the collection site when requested. It is the responsibility of the collector to provide all necessary contact information on the VS Form 10-4.
    - If all animals tested in the lot are rapid screening test negative, the designated laboratory will report back to the collector and, when requested, to the management at the collection site that all animals in the specific lot are screening test negative. If any of the animals in the lot are screening test suspect, then the designated laboratory report will specify which carcasses tested suspect to the VS Area Office and the management at the collection site.

- Screening test suspects will be tested using IHC or western blot for confirmation through NVSL facilities. Samples from all screening test suspects must be immediately forwarded to NVSL, with prior notification and confirmed arrival. All confirmatory test results will be transmitted to the VS Area Office so that carcass disposal can be coordinated and verified. The AVIC will contact the sample collector and the facility where the sample was collected.
- Presumptive positives will be handled in accordance with the BSE response plan.

Disposal

1. Disposal of carcasses and offal – Disposal of carcasses and offal will be in compliance with Federal, State, and local laws. Acceptable options may include:
    - Refrigerate or freeze pending test results, then render or otherwise process after negative test results obtained (could include boning out carcass and holding the meat product for use in pet food or rendering materials and holding finished product).
    - Disposal by rendering at dedicated facilities, if available – rendering for non-animal feed use, such as biofuel or cement.
    - Burial in a landfill or on-the-farm.
    - Alkaline digestion.
    - Incineration.

2. Hides – Hides need not be disposed or held pending test results.

3. Sample disposal – Laboratories will dispose of samples using standard operating procedures.

Education and Outreach

Significant efforts in education and outreach will be necessary to achieve the goals of this surveillance plan. APHIS will enhance existing educational materials and processes and work with other Federal and State agencies as outlined in Appendix A. These outreach efforts will inform producers and affiliated industries of our surveillance goals, and will encourage reporting of suspect or targeted cattle on farm and elsewhere.

B. Additional Sampling Plan for Clinically Normal Aged Cattle

Surveillance Objective

In addition to sampling the high-risk population, it has been determined that a sampling of clinically normal, aged slaughter cattle be included in the U.S. BSE surveillance plan. This is based on the scientific knowledge that BSE is primarily a disease of older animals, and thus it will focus on clinically normal aged animals presented for slaughter.

Population Estimates and Distribution of Clinically Normal Adult Slaughter Cattle

According to the NASS Livestock Slaughter 2002 Summary, U.S. commercial cattle slaughter during 2002 totaled 35.7 million head, with Federal inspection comprising 98.3 percent of the total. The target population of clinically normal adult cattle (bulls, dairy cows, and other cows) comprised 17.8 percent of cattle slaughtered under Federal inspection. This is equal to approximately 6.2 million adult cattle. Out of this population, a total of 20,000 samples will be obtained from aged animals.

To obtain a sampling distribution for 20,000 BSE slaughter samples from healthy adult bulls and cows, USDA-FSIS fiscal year 2003 data were utilized. The total number of bulls and cows slaughtered in 40 plants was 5,382,313 cattle (4,885,855 cows and 496,458 bulls), accounting for approximately 86 percent of annual totals for federally inspected plants. Sampling efforts can be concentrated in these 40 plants to achieve the most efficient sampling schedule while maintaining access to a significant proportion (86 percent) of the population. A sampling distribution was determined by generating plant-level percentage contributions to the total cattle slaughtered in these 40 plants, which ranged from 20,033 to 368,482 cattle per year. The 40 plants identified are located in 17 States. Some of these States only have one plant identified (Arizona, Georgia, Idaho, Michigan, Missouri, South Carolina, South Dakota, and Utah), and some states have more than one (California, Minnesota, Ohio, North Carolina, Nebraska, Pennsylvania, Texas, Washington, and Wisconsin).

Sample Collection for Clinically Normal Aged Slaughter Cattle

Sample collection would be conducted by FSIS employees who would target, via visual inspection, cattle that appear to be the oldest. As necessary, APHIS employees or contractors could assist with sample collection in identified slaughter facilities. All of the previously described points on sample collection, training, and communication are applicable in this portion of the sampling plan.

BSE Education, Training, and Outreach Matrix

Audience	Key Messages/Objectives	Outreach Products	Training/Education
Accredited Veterinarians	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Sample collection and handling Risk communication	Outreach kit Web site Video PSA	BSE sampling training materials CD-ROM
Federal Veterinarians/ Animal Health Technicians	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Certification of slaughter plants and renderers Animal traceback processes Recognition and diagnosis of TSEs Surveillance sampling Risk communication	Outreach kit Video PSA	BSE sampling training materials CD-ROM Foreign Animal Disease Diagnostician (FADD) schools Foreign Animal Disease (FAD) web-based training Satellite seminars on animal traceback
State Veterinarians	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Sample collection and handling Recognition and diagnosis of TSEs Risk communication	Outreach kit Video PSA	FADD schools FAD web-based training Satellite seminars on animal traceback

Audience	Key Messages/Objectives	Outreach Products	Training/Education
FSIS Inspectors	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Certification of slaughter plants and renderers Surveillance sampling	Outreach kit	BSE sampling training materials CD-ROM
Industry & Producer Organizations	BSE surveillance BSE disease information USDA actions on BSE	Outreach kit Web site Video PSA	Materials provided in outreach kit contain educational information appropriate for this audience
National Association of State Departments of Agriculture	BSE surveillance BSE disease information USDA actions on BSE	Outreach kit PowerPoint presentation	Materials provided in outreach kit contain educational information appropriate for this audience
Producers	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Handling of downer animals Contact information for testing	Outreach kit Web site	Materials provided in outreach kit contain educational information appropriate for this audience
Livestock Markets	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Handling of downer animals Contact information for testing	Outreach kit Web site	Materials provided in outreach kit contain educational information appropriate for this audience

Audience	Key Messages/Objectives	Outreach Product	Training/Education
USDA extension, 4-H, FFA, FSA, Ag Colleges, VoAg Teachers, Farm Bureau	BSE surveillance BSE disease information USDA actions on BSE	Outreach kit PowerPoint presentation	Materials provided in outreach kit contain educational information appropriate for this audience
Veterinary Schools	Outreach: BSE surveillance BSE disease information USDA actions on BSE Education: Recognition and diagnosis of TSEs	Outreach kit PowerPoint presentation	FAD web-based training
Ag Media	BSE disease information USDA actions on BSE	Press kit Press releases Editorials	
General Public	BSE disease information USDA actions on BSE	Outreach kit Radio PSA Advertising	

Introduction

A generic state-level plan is included. You will need to consult your specific state's plan for the target number of samples, financial information, and other details. The AVIC in each state can provide your specific state plan.

National BSE Plan – State Surveillance Proposal Sample

Background

The Animal and Plant Health Inspection Service (APHIS), in cooperation with the Food Safety Inspection Service (FSIS), and the Food and Drug Administration (FDA), has developed an outline for an intensive national BSE surveillance plan. This one-time effort will give a snapshot of the cattle population in the US and help to define whether BSE is actually present in the population and if so, at what level. The goal of this plan is to test as many cattle in the targeted high-risk population as possible in a 12-18 month period.

The current state BSE Surveillance plan estimated the collection of xxxx to xxxx samples for FY 2004. This new one-time initiative represents an increase of four to five times that amount. A rough projection of the number of samples needed from this state is xxxx to xxxx. If the state's cattle are sampled in another state there will be an effort to capture that data and count surveillance numbers bases on state of origin whenever possible.

Note: All costs in this document are rough estimates.

Plan

This plan will budget for the higher targeted estimate of xxxx samples. However, based on current surveillance practices and rates it is realistically expected that about xxxx samples can be collected in a 12 month period. In order to acquire samples from some of the alternative sources additional costs will likely be incurred. The bulk of the samples will no longer be available at a single facility and we anticipate that to acquire the desired sample volume multiple small facilities will be involved, if they agree to cooperate and logistics are feasible. Additional efforts will also be made to obtain on-farm samples from clinical or downer animals using private practitioners and possibly farm calls by animal health personnel. An intensified educational/outreach program will also be initiated in an effort to stimulate awareness and reporting by producers. A brief description of sample source, expense, and resource categories is provided.

Sample Sources

Renderer – Several rendering plants that pick up cattle will either collect samples for us or will retain the heads and animal identification for state or federal animal health personnel to sample. Plants that retain the heads or carcasses for us but do not agree to do the sampling will be paid a small carcass holding fee ($xx-xx). Plants that agree to be trained and collect samples for us will be paid a fee for this service ~$ xx-xx. The price per sample may be adjusted if circumstances occur which create more labor and inconvenience to the facility.

3D - 4D Plants – Several (x) pet food type plants that pick up dead, down, diseased or other disabled stock (4D plants) will either collect samples for us or will retain the heads and animal identification for state or federal animal health personnel to sample. Plants that retain the heads

or carcasses for us but do not agree to do the sampling will be paid a small carcass holding fee ($xx-xx). Plants that agree to be trained and collect samples for us will be paid a fee for this service ~$ xx-xx. The price per sample may be adjusted if circumstances occur which create more labor and inconvenience to the facility. Due to the range in price for various situations the average of $xx per sample will be used to calculate costs for the 4D plants.

Slaughter Plants (Federal, State, and Custom-exempt) – While the main slaughter facility in this state no longer accepts downer animals, occasionally animals do become non-ambulatory during transport or shortly after arrival. These are animals that we would like to sample. Costs that may be incurred in order to gain access to these samples include holding costs, most likely in the form of a reefer truck, and/or transportation to a suitable 4D plant where samples can be collected.

Private Veterinarians (on-farm) (25) – There are about xx accredited large animal veterinarians who would like to contract to collect on-farm samples. Efforts in this regard to date indicate that one practitioner may collect 1-2 samples per month, but this may increase seasonally. Currently the fee paid to a practitioner is $xxx per testable sample (no disposal costs to producer factored in). It is anticipated that with increased participation in this program that some disposal costs may be incurred if on-site disposal is not possible. The cost associated with transportation/disposal of such animals is estimated to be $xxx to xxx depending on the location of the premises and method of disposal.

On Farm – other – Providing cost offset for disposal/transport of animals eligible for testing may encourage producers to request testing for their down and fresh dead animals. This category is intended to attempt to gain access to on-farm down and dying animals which owners would otherwise dispose of on-site without veterinary consultation. The cost associated with transportation/disposal of such animals is estimated to be $xxx to xxx depending on the location of the premises and method of disposal. In these types of situations it will be attempted to funnel these animals to one of the 4D plants that are conducting sampling.

Livestock Markets – Occasionally animals will become non-ambulatory while they are in the market. Costs related to these types of cases will involve personnel time and travel and potentially some transportation or disposal cost ($xxx to xxx).

Diagnostic Labs – The State Veterinary Diagnostic laboratories, the state university School Of Veterinary Medicine, and Department of Health rabies laboratories may potentially be the source of a few BSE surveillance samples. Transport of animals to the labs and disposal costs (usually on-site incineration or tissue digestion) are roughly estimated to be $xxx per animal.

Costs and Resource Needs

Transportation costs – Transportation of animals to sampling and/or disposal sites may be variable and may range from $xxx to xxx depending on the location of the animal and/or method of disposal. Due to numerous variables the costs are calculated based on the higher estimate of $xxx.

Disposal costs – When circumstances occur where rendering is not possible, alternative disposal options will be pursued. It is projected, based on the current field situations, that landfill disposal will be required for some offal and carcasses. Due to numerous variables that will affect decisions to landfill or not it is difficult to accurately predict these costs. To account for some expense in this area, an estimate of x to x ton per week at $xx per ton, for three 4D facilities was used to obtain an approximation of $xx per sample (using the lower collection rate).

Holding costs – Due to the constraints of the rendering company, offal and/or carcasses and product may be required to be held until negative results are returned. This affects 4D and slaughter plants, none of which currently have adequate cold storage to retain the volume of material that is involved. Rental of reefer truck would enable the sampling process and plant operations to continue to flow. Unanticipated costs related of holding of carcasses or offal have been factored into the per sample costs.

Sample shipping/ courier costs – Most sampling situations now require a rapid return on the results to minimize the impact of holding carcasses or offal. This will entail an increased amount of overnight express mailing of fresh tissue samples. Funds requested in the budget are based on an estimated xxx shipments @ $xx each for FedEx overnight shipping. A courier will be needed for sample delivery to the state university laboratory to improve the speed of getting results.

Producer and Public Education – The State University Extension Office plans to assist our effort by conducting producer education and public awareness programs throughout the state. The focus of these efforts is to increase producer awareness and encourage owners to request testing on eligible animals. Through these efforts it is hoped that additional on-farm samples may be obtained.

Budget

This budget represents the total cost to obtain the target sample numbers and is based on calculations for a 12 month time frame and collection of the higher sample target of approximately xxxx samples. If surveillance continues 12-18 months then the costs would be spread over that time in proportion to the number of samples actually collected.

Estimated per sample costs are aggregates which account for different provisions depending on the facility and the particular arrangement that works at each particular location. Some costs estimates were calculated based on weekly or monthly projections. In these situations the per-sample estimated costs would be affected by the total samples collected (higher per-sample cost for fewer samples).

XXXXX VS Surveillance Rates and Costs to Meet National BSE Plan

Sample Source (may be by type of collector or specific facility)	Yearly Samples	Per Sample Collection Fees	Carcass Disposal/ Storage Fee*	Specify if Disposal or Storage	Average Carcass Transport Fee	Total per sample cost	Total Estimated Fees
4D Plants	xxxx	$ xx	$xx	Storage	$ xx	$ xxx	$ xxxx
Slaughter Plants	xxx	$ xx	$xx	Storage	$ xx	$ xxx	$ xxxxx
Private Vets (on-farm)	xxxx	$ xxx	$xxx	Disposal – landfill	$xxx	$ xxx	$ xxxxx
On Farm – other	xxx	$ xx	$xxx		$xxx	xxx	$ xxxxx
Diagnostic Labs	xx		$xxx	Disposal - incineration		$ xxx	$ xxxx
Livestock Markets	xx		$xxx	Disposal	$xxx	$ xxx	$ xxxx
Subtotal	**xxxx**						***$ xxxxxxxx***
Additional costs:	Training and education						$ xxxx
							$ xxxx
	FedEx Overnight (xxx @$xx)_						$ xxxx
	Travel costs to training and meetings						$ xxxx
	Supplies						$ xxxxx
Personnel:	**x AHTs to collect in plants, x data entry clerk GS 5**						
Subtotal							***$ xxxxxxx***
Total							***$ xxxxxxx***

Note: All values represent estimates and may include one or more facilities. Per-sample costs are the expected expenses that would be incurred in order to obtain the sample (does not include shipping or courier costs, or the costs to run the test). Subtotal for samples is for 12 month period.

*Disposal and Storage fees should not be charged for the same sample – either one or the other.

Additional assistance in collecting on-farm samples and collecting 4D plant samples will be provided by state personnel. The following associated costs are anticipated.

XXXXX Cooperative BSE work		
Item	**Description**	**Total Annual Cost**
Training	Provide training for about xx State personnel on collection, submission, and safety regarding the BSE sampling. Estimate this would involve x days of travel and work time for employees with a cost of $xxxx. Equipment and supply costs were estimated to be $xxx per employee (xx employees).	$ xxxx
State BSE work conference	Work conference for all state field personnel in conjunction with BSE sample collection training. Cost of xx personnel at $xx per day times x days = $xxxxxx.	$ xxxxx
Collection/pick-up at 4D and slaughter plants	State assistance in collecting and/or picking up samples from 4D plants estimated at xx employees/days/month at $xxx/day or total $xxxx per month.	$ xxxxx
On-Farm Collection	The number of on farm sample collection and/or pickup seems fine. Based on xx miles travel at xx per mile ($xxxx), plus x hours for travel, sample collecting and reporting at $xxx per hour = $xxxxxx for a total of $xxxxx per visit. xx times $xxxxx would equal $xxxx per month.	$ xxxxxx
Total		***$ xxxxxxx***

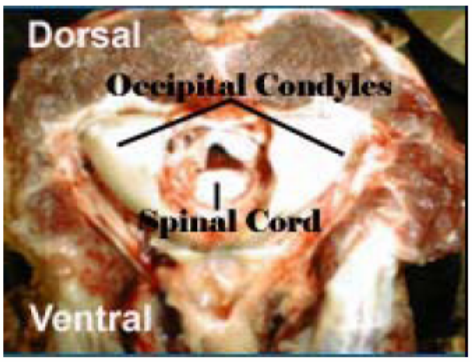
Total for State and Federal Surveillance Efforts: $ xxxxxxxx

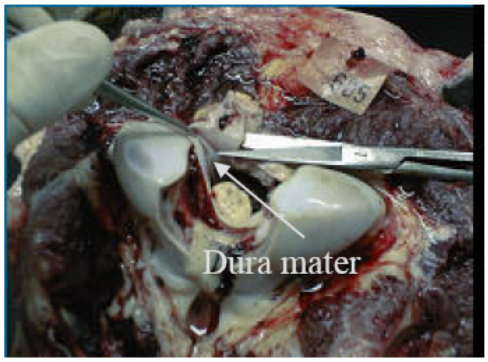
BSE Surveillance Sampling Plan for: XXXX

Item	Collection Site Type	Name or ID of Collection site	Number of animals processed	Estimated total samples	Per sample collection fees	Carcass Disposal or Storage Fee*	Specify if Disposal or Storage is used	Average Carcass Transport Fee	Other fees (per sample)	Specify type of other fee	Total cost per sample	Total
											0	0
1	Rendering										0	0
											0	0
											0	0
2	3D-4D plant										0	0
											0	0
											0	0
3	Slaughter (Fed/State/custom)										0	0
											0	0
											0	0
4	State Dx lab										0	0
											0	0
											0	0
5	Public Health lab										0	0
											0	0
											0	0
6	FAD/CNS cases										0	0
											0	0
											0	0
7	Livestock markets										0	0
											0	0
											0	0
8	On-farm calls										0	0
											0	0
											0	0
9	Other										0	0
											0	0
*Disposal and Storage fees should not be charged for the same sample – either one or the other should be used in calculations.												

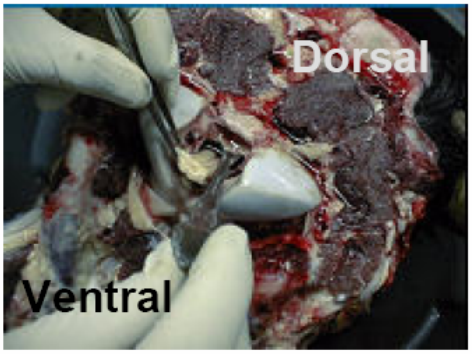
	Estimated personnel needs									
	GS 5/7 FTE's Total	FTE's Federal (existing/proposed)	FTE's State (existing/proposed)	FTE's Private (existing/proposed)						
You only need to supply this information if you did not do so previously or would like to change what you previously submitted										
At this point we are not including personnel in the budget request. Similar to the last round of BSE CCC, GS5/7 level term positions will be provided.										
If you need positions that are not equivalent to these, please provide additional justification in the space below.										

		Additional Expenses	**# of units (if applic)**	**cost per unit (if applic)**	**Total cost**
		Cooperative agreement activities - provide description			**Total cost**

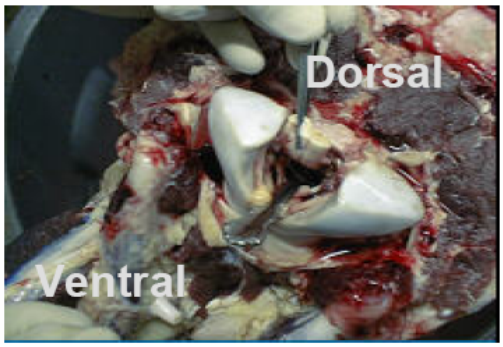




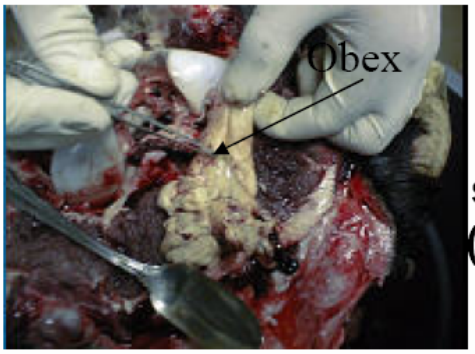
•Cut dura mater and cranial nerves; remove dura



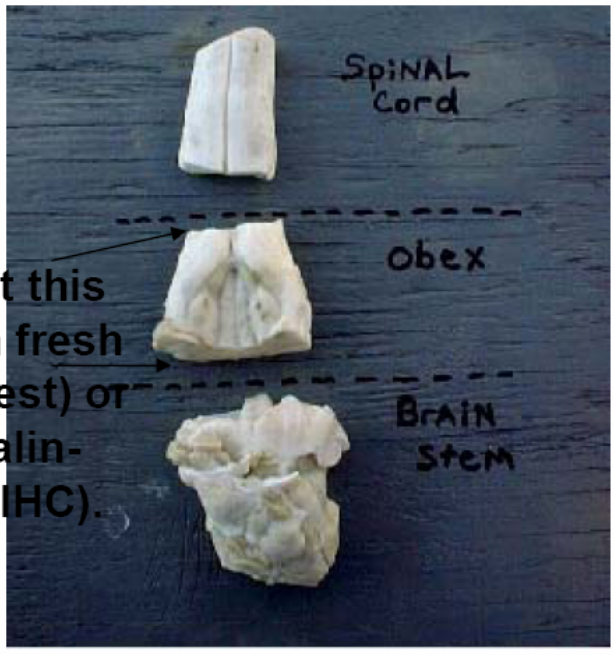
•Pull spinal cord ventrally, insert spoon dorsally
•Insert spoon straight in with a scooping motion; do not rock spoon or turn from side to side



•Pull spinal cord dorsally, insert spoon ventrally
•Cut cord with spoon

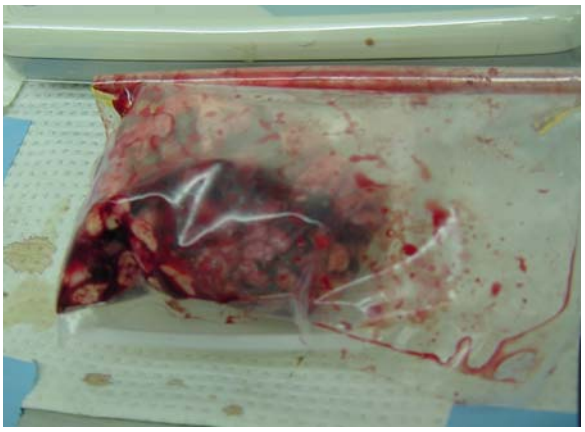


Submit this section fresh (rapid test) or formalin-fixed (IHC).



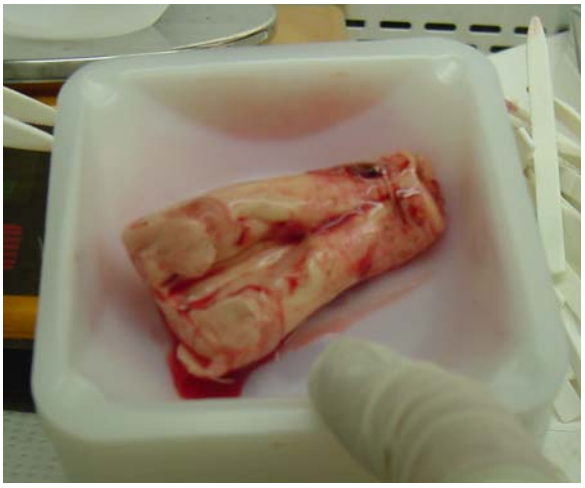
APHIS

Taking a Quality Sample

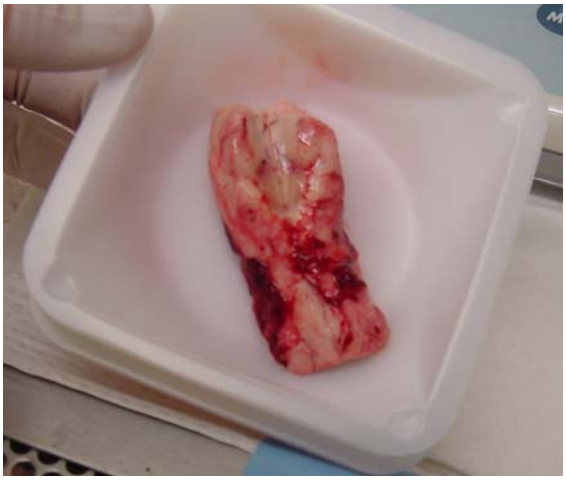


DO NOT USE WHIRL PACKS

Send It in Tubes Only

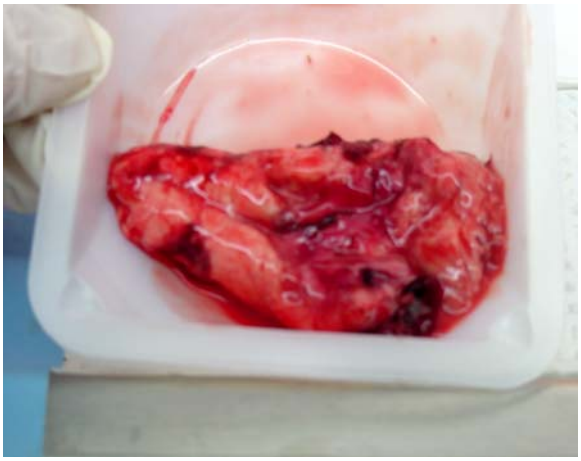


Excellent Sample Condition

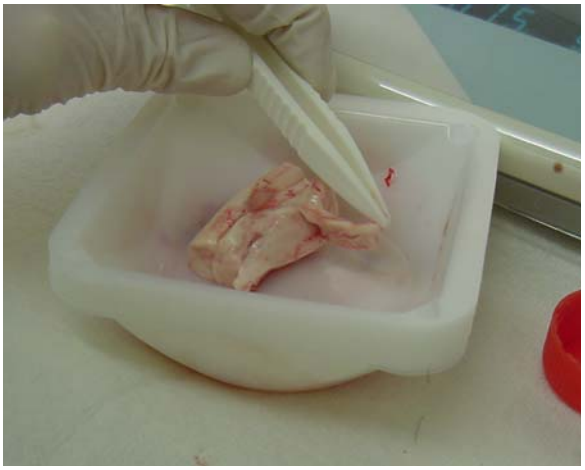


Good Sample Condition

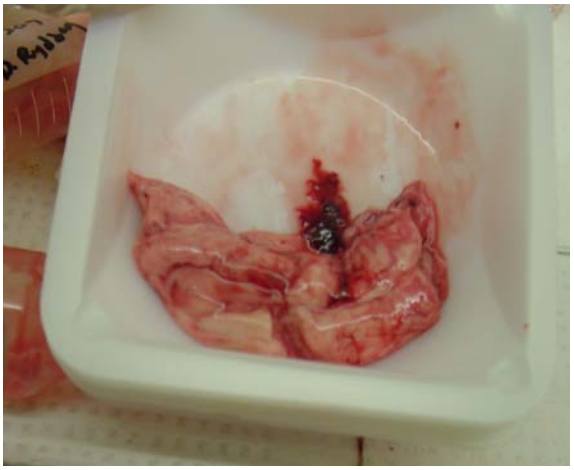
Good Sample with Slight Autolysis



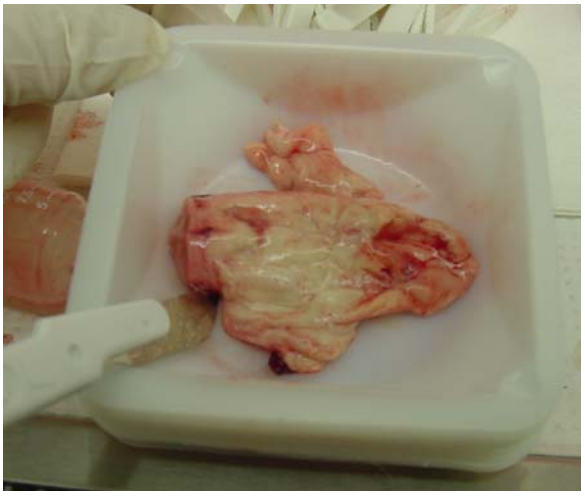
Fair Sample with Distinct Autolysis



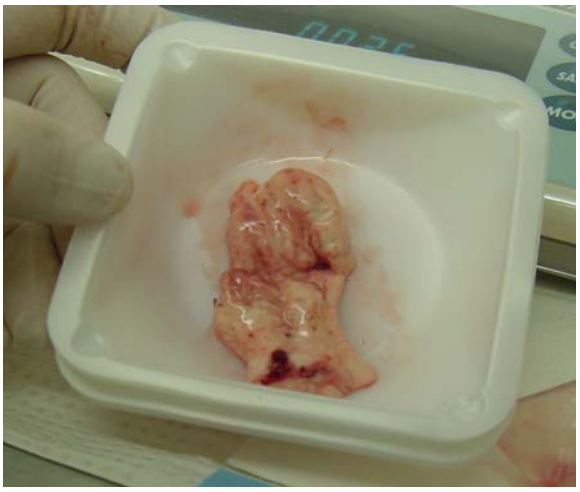
Mutilated Sample with No Autolysis



Mutilated Sample with No Autolysis
ID Questionable

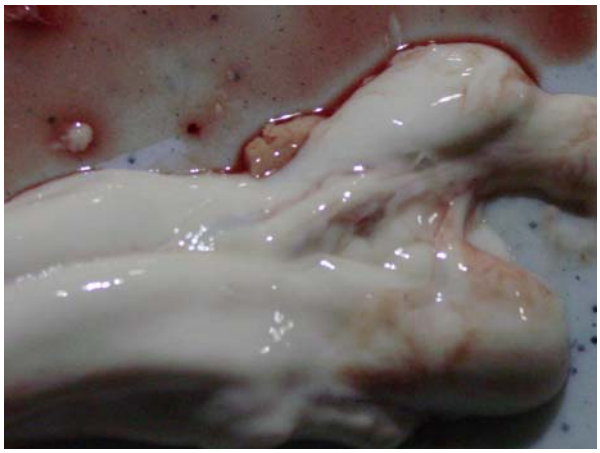


Mutilated Sample with Slight Autolysis
ID Questionable



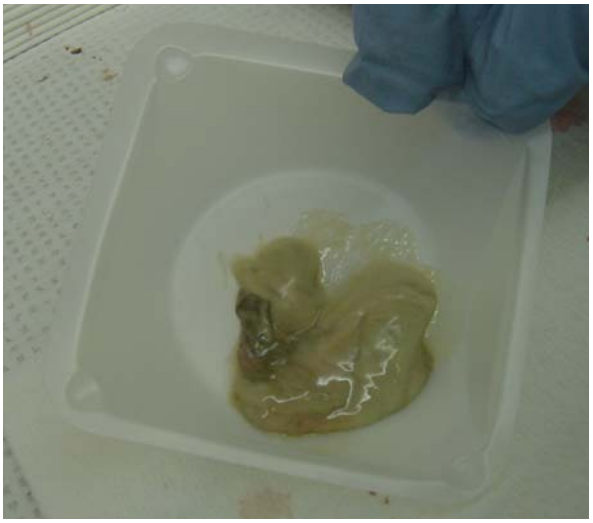
Mutilated Sample with Slight Autolysis
ID Questionable

NOTE: Questionable ID samples will be tested and reported as ND/NO (not detected / not obex). Although PrPres was not detected in this sample, the specimen could not definitely be identified as the preferred location recommended for testing (the medulla at the obex). Therefore, the significance of these results is unknown.

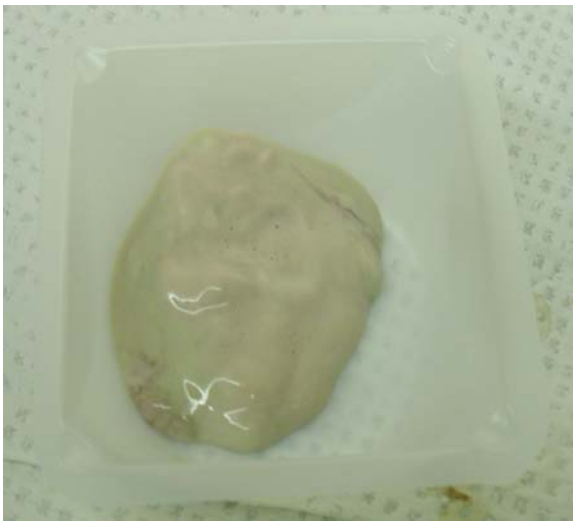


Mutilated Sample with Advanced Autolysis
Not Identifiable

Mutilated Sample with Advanced Autolysis
Not Identifiable

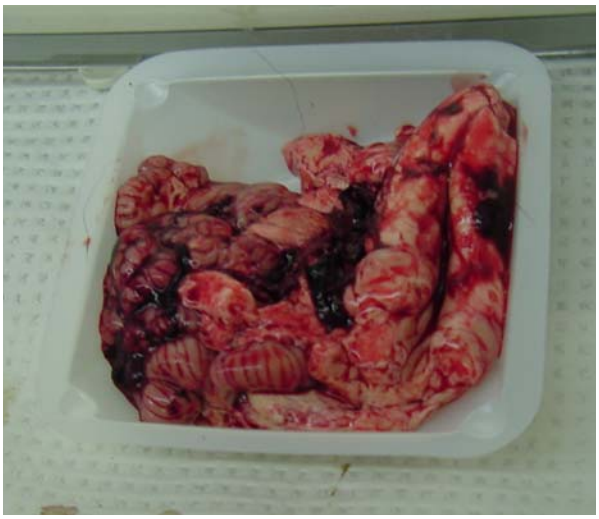


Mutilated Sample with Advanced Autolysis
Not Identifiable

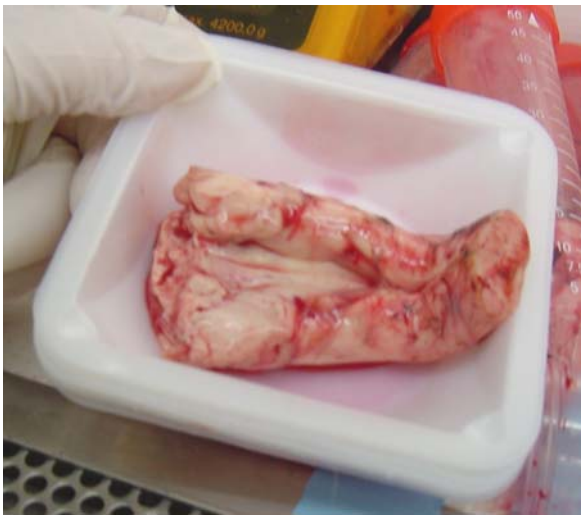


Liquid State

NOTE: Samples that are too autolyzed (liquid) to recognize the area of the brain will not be tested. For samples that are already showing some autolysis at the time of collection, it may be prudent to fix such samples in formalin and submit them for testing by IHC rather than by ELISA.

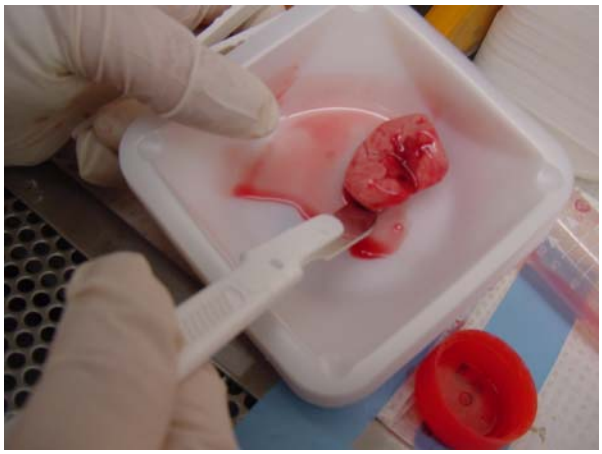


Too Much Tissue Submitted

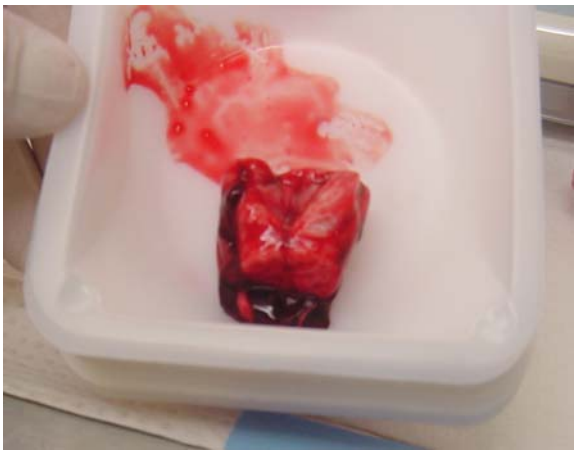


Too Much Tissue Submitted

NOTE: While some excess tissue is okay (the second photo), there have been cases where the sample is compressed and mutilated because the excess tissue was forced into the tube.

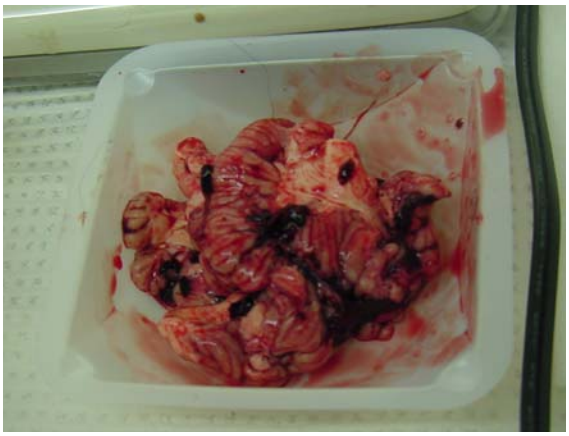


Too Little Tissue Submitted

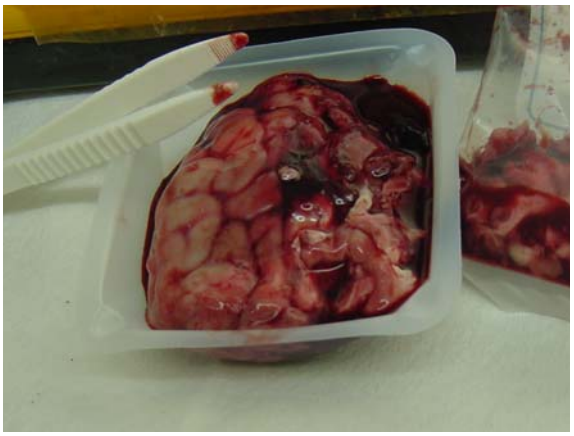


Too Little Tissue Submitted

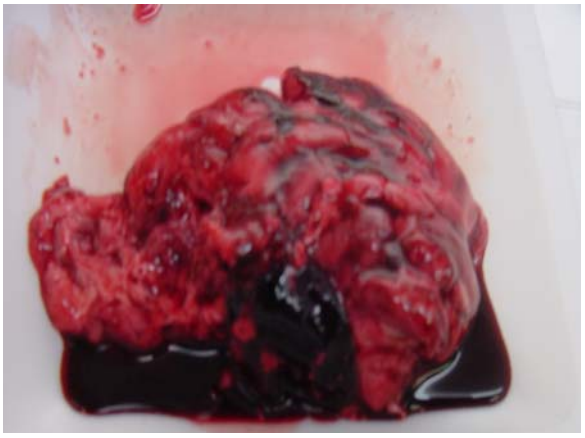
NOTE: The samples in these photos are suitable for ELISA testing and if negative by ELISA there would not be a problem, but if the results were inconclusive then it would be difficult to process for IHC and additional testing.



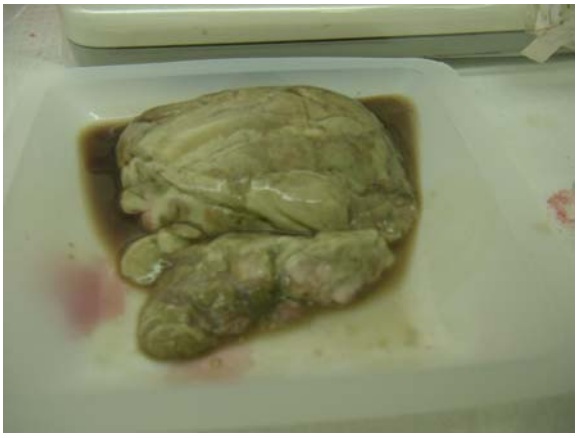
Do Not Send Cerebellum



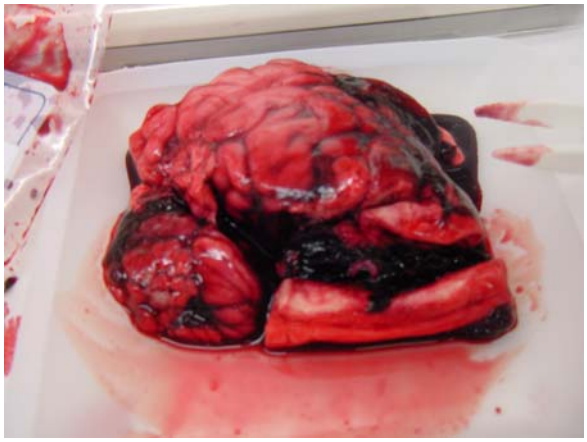
Do Not Send Cerebrum



Do Not Send Cerebrum



Do Not Send Cerebrum



Do Not Send Cerebrum

Unacceptable Quality – DO NOT SUBMIT

NOTE: The samples with cerebrum, cerebellum, and those that are too autolyzed (liquid) to recognize the area of the brain will not be tested.

AVIC Directory

Alabama
Dr. O. W. Hester
USDA, APHIS, VS
P.O. Box 70429
Montgomery, AL 36107
(334) 223-7141
Fax (334) 223-7352
Owen.Hester@aphis.usda.gov

Alaska
Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW, Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@aphis.usda.gov

Arizona
Dr. Hortentia Harris
USDA, APHIS, VS
1400 E. Southern Ave., Suite 245
Tempe, AZ 85282
(480) 491-1002
Fax (480) 491-1895
Hortentia.D.Harris@aphis.usda.gov

Arkansas
Dr. Ronnie Blair
USDA, APHIS, VS
1200 Cherry Brook Dr., Suite 300
Little Rock, AR 72211
(501) 224-9515
Fax (501) 225-5823
Ronnie.E.Blair@aphis.usda.gov

California
Dr. Paul Ugstad
USDA, APHIS, VS
9580 Micron Ave., Suite E
Sacramento, CA 95827
(916) 857-6170
Fax (916) 857-6196
Paul.O.Ugstad@aphis.usda.gov

Colorado
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
755 Parfet Street, Suite 136
Lakewood, CO 80215
(303) 231-5385
Fax (303) 231-5390
VSCO@aphis.usda.gov

Connecticut
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
VSMA@aphis.usda.gov

Delaware
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
1598 Whitehall Road, Suite A
Annapolis, MD 21401
(410) 349-9708
Fax (301) 261-8113
VSMD@aphis.usda.gov

District of Columbia
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
1598 Whitehall Road, Suite A
Annapolis, MD 21401
(410) 349-9708
Fax (301) 261-8113
VSMD@aphis.usda.gov

Florida
Dr. Robert E. Southall
USDA, APHIS, VS
7022 NW 10th Place
Gainesville, FL 32605-3147
(352) 333-3120
Fax (352) 333-6849
VSFL@aphis.usda.gov

Georgia
Dr. Edgardo Arza
USDA, APHIS, VS
1498 Klondike Rd., Suite 200
Conyers, GA 30094
(770) 922-7860
Fax (770) 483-9000
VSGA@aphis.usda.gov

Hawaii
Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW., Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@aphis.usda.gov

Idaho
Dr. Cynthia Gaborick
USDA, APHIS, VS
9158 West Black Eagle Drive
Boise, ID 83709
(208) 378-5631
Fax (208) 378-5637
VSID@aphis.usda.gov

Illinois
Dr. Lennis Knight
USDA, APHIS, VS
2815 Old Jacksonville Rd., Suite 104
Springfield, IL 62704
(217) 241-6689
Fax (217) 241-6695
Lennis.C.Knight@aphis.usda.gov

Indiana
Dr. Francisco Collazo Mattei
USDA, APHIS, VS
6960 Corporate Drive
Indianapolis, IN 46278-1928
(317) 290-3300
Fax (317) 290-3311
Francisco.Collazo-Mattei@aphis.usda.gov

Iowa
Dr. Kevin L. Petersburg
USDA, APHIS, VS
Federal Bldg., Rm. 891
210 Walnut Street
Des Moines, IA 50309
(515) 284-4140
Fax (515)284-4156
Kevin.L.Petersburg@aphis.usda.gov

Kansas
Dr. Kevin P. Varner
USDA, APHIS, VS
1947 NW Topeka Blvd., Suite F
Topeka, KS 66608
(785) 235- 2365
Fax (785) 235-1464
Kevin.P.Varner@aphis.usda.gov

Kentucky
Dr. Roger J. Odenweller
USDA, APHIS, VS
P.O. Box 399
Frankfort, KY 40602
(502) 227-9651
Fax (502) 223-7121
Roger.Odenweller@aphis.usda.gov

Louisiana
Dr. Joel Goldman
USDA, APHIS, VS
5825 Florida Blvd., Rm 1140
Baton Rouge, LA 70806-9985
(225) 389-0436
Fax (225) 389-0524
Joel.Goldman@aphis.usda.gov

Maine
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
VSMA@aphis.usda.gov

Maryland
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
1598 Whitehall Road, Suite A
Annapolis, MD 21401
(410) 349-9708
Fax (301) 261-8113
VSMD@aphis.usda.gov

Massachusetts
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
William.G.Smith@usda.gov

Michigan
Dr. Reed Macarty
USDA, APHIS, VS
3001 Coolidge Road, Suite 325
East Lansing, MI 48823
(517) 324-5290
Fax (517) 324-5289
Reed.E.Macarty@aphis.usda.gov

Minnesota
Dr. Michael L. Stine
USDA, APHIS, VS
251 Starkey Street
Bolander Bldg., Suite 229
St. Paul, MN 55107
(651) 290-3691
Fax (651) 228-0654
Michael.L.Stine@aphis.usda.gov

Mississippi
Dr. Charles P. Nettles
USDA, APHIS, VS
345 Keyway Street
Flowood, MS 39232
(601) 965-4307
Fax (601) 965-5535
Charles.Nettles@aphis.usda.gov

Missouri
Dr. Robert L. Fischer
USDA, APHIS, VS
P.O. Box 104418
Jefferson City, MO 65110-4418
(573) 636-3116
Fax (573) 636-4384
VSMO@aphis.usda.gov

Montana
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
208 North Montana Ave., Suite 101
Helena, MT 59601-3837
(406) 449-5407
Fax (406) 449-5439
VSMT@aphis.usda.gov

Nebraska
Dr. Kathleen Akin
USDA, APHIS, VS
P.O. Box 81866
Lincoln, NE 68501
(402) 434-2300
Fax (402) 434-2330
VSNE@aphis.usda.gov

Nevada
Dr. Paul Ugstad
USDA, APHIS, VS
9580 Micron Ave., Suite E
Sacramento, CA 95827
(916) 857-6170
Fax (916) 857-6196
Paul.O.Ugstad@aphis.usda.gov

New Hampshire
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
VSMA@aphis.usda.gov

New Jersey
Dr. Jonathan Zack
USDA, APHIS, VS
Mercer Corporate Park
320 Corporate Blvd.
Robbinsville, NJ 08691-1598
(609) 259-8387
Fax (609) 259-2477
Jonathan.T.Zack@aphis.usda.gov

New Mexico
Dr. Michael T. Greenlee
USDA, APHIS, VS
6200 Jefferson Street, NE, Suite 117
Albuquerque, NM 87109
(505) 761-3160
Fax (505) 761-3176
Michael.T.Greenlee@aphis.usda.gov

New York
Dr. Roxanne Mullaney
USDA, APHIS, VS
One Winners Circle, Suite 100
Export/Area Office
Albany, NY 12205
(518) 453-0187
Fax (518) 453-0213
Roxanne.C.Mullaney@aphis.usda.gov

North Carolina
Dr. Eric Coleman
USDA, APHIS, VS
930 Main Campus Drive, Suite 200
Raleigh, NC 27606
(919) 855-7700
Fax (919) 855-7720
Export Line (919) 855-7701
VSNC@aphis.usda.gov

North Dakota
Dr. Larry A. Schuler
USDA, APHIS, VS
3509 Miriam Ave., Suite B
Bismarck, ND 58501
(701) 250-4210
Fax (701) 250-4471
Larry.A.Schuler@aphis.usda.gov

Ohio
Dr. Susan Skorupski
USDA, APHIS, VS
12927 Stonecreek Drive
Pickerington, OH 43147
(614) 469-5602
Fax (614) 866-1086
VSOH@aphis.usda.gov

Oklahoma
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
4020 North Lincoln Blvd., Suite 101
Oklahoma City, OK 73105
(405) 427-9413
Fax (405) 427-9451
VSOK@aphis.usda.gov

Oregon
Dr. Don Herriott
USDA, APHIS, VS
530 Center St., NE, Suite 335
Salem, OR 97301
(503) 399-5871
Fax (503) 399-5607
Don.E.Herriott@aphis.usda.gov

Pennsylvania
Dr. Enzo R. Campagnolo
USDA, APHIS, VS
2301 N. Cameron St., Rm. 412
Harrisburg, PA 17110
(717) 782-3442
Fax (717) 782-4098
Enzo.R.Campagnolo@aphis.usda.gov

Puerto Rico
Dr. Miguel A. Borri-Diaz
USDA, APHIS, VS
IBM Building
654 Munoz Rivera Avenue, Suite 700
Hato Rey, PR 00918
(787) 766-6050
Fax (787) 766-5159
VSPR@aphis.usda.gov

Rhode Island
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
VSMA@aphis.usda.gov

South Carolina
Dr. Delorias Lenard
USDA, APHIS, VS
9600 Two Notch Road, Suite 10
Columbia, SC 29229
(803) 788-1919
Fax (803) 788-2102
VSSC@aphis.usda.gov

South Dakota
Dr. Lynn. A. Tesar
USDA, APHIS, VS
314 S. Henry, Suite 100
Pierre, SD 57501-0640
(605) 224-6186
Fax (605) 224-8451
Lynn.A.Tesar@aphis.usda.gov

Tennessee
Area Veterinarian-in-Charge - Vacant
USDA, APHIS, VS
P.O. Box 110950
Nashville, TN 37222
(615) 781-5310
Fax (615) 781-5309
VSTN@aphis.usda.gov

Texas
Dr. Jerry W. Diemer
USDA, APHIS, VS
Thornberry Bldg., Rm. 220
903 San Jacinto Blvd.
Austin, TX 78701
(512) 916-5551
Fax (512) 916-5197
Jerry.W.Diemer@aphis.usda.gov

Utah
Dr. Robert A. DeCarolis
USDA, APHIS, VS
176 N. 2200 West, Suite 230
Airport Park, Bldg. #4
Salt Lake City, UT 84116
(801) 524-5010
Fax (801) 524-6898
Robert.A.DeCarolis@aphis.usda.gov

Vermont
Dr. William G. Smith
USDA, APHIS, VS
160 Worcester-Providence Road
Sutton Square Plaza, Suite 20
Sutton, MA 01590-9998
(508) 865-1421, 22
Fax (508) 865-9317
VSMA@aphis.usda.gov

Virginia
Dr. Terry L. Taylor
USDA, APHIS, VS
Washington Bldg., 6th Floor
1100 Bank Street
Richmond, VA 23219
(804) 771-2774
Fax (804) 771-2030
VSVA@aphis.usda.gov

Washington
Dr. Gary L. Brickler
USDA, APHIS, VS
2604 12th Court, SW., Suite B
Olympia, WA 98502
(360) 753-9430
Fax (360) 753-9585
Gary.L.Brickler@aphis.usda.gov

West Virginia
Dr. Susan Skorupski
USDA, APHIS, VS
12927 Stonecreek Drive
Pickerington, OH 43147
(614) 469-5602
Fax (614) 866-1086
VSOH@aphis.usda.gov

Wisconsin
Dr. Linn Wilbur
USDA, APHIS, VS
6510 Schroeder Road, Suite 2
Madison, WI 53711
(608) 270-4000
Fax (608) 270-4001
Linn.A.Wilbur@aphis.usda.gov

Wyoming
Dr. Bret A. Combs
USDA, APHIS, VS
5353 Yellowstone Road, Room 209
Cheyenne, WY 82009
(307) 772-2186
Fax (307) 772-2592
Bret.A.Combs@aphis.usda.gov

Sample Documentation and Submission: Filling Out the Paper Forms

I. General

The new USDA BSE Surveillance Submission Form (Revision 08/12/04) and the USDA BSE Surveillance Submission Continuation Form (Revision 08/12/04) are to be used in place of the VS Form 10-4 and VS 10-4(a); the new USDA BSE Surveillance Data Collection Form (Revision 08/12/04) is to be used in place of the Supplemental Form for Brain Tissue Submission. Instructions for completion of these forms are provided below. Instructions are also provided on comparing the revised paper forms to the Web-based data entry screens in the BSE Surveillance Information System.

Subsequent to sample collection by the collector, the following forms should be thoroughly and accurately completed to ensure proper documentation, data entry, and submission of information concerning the samples sent to the appropriate laboratory for BSE testing. Submitters should use their professional judgment in reporting any information not directly observed, such as signs of clinical illness, or anything that was estimated, such as age of animal sampled.

Examples of the forms are shown in Attachment A and Attachment B in this Appendix. Copies of the forms are available for download at:
http://www.aphis.usda.gov/vs/nvsl/specimencollectionbse.htm

II. Completion of the paper "USDA BSE Surveillance Submission Form"

NOTE: A separate submission form must be completed for each collector, collection site, or collection date.

Collection Site Type: Mark type of location at which the sample(s) was collected. If samples are collected from more than one site type, a separate submission form must be used for each set of samples.

Reserved for Testing Laboratory Accession or Identification Label: This section is reserved for the testing laboratory use. Do not mark in this area.

BSE Referral Number: Write in the Referral Number. The BSE Referral Number is used to associate the BSE Surveillance Submission Form to the BSE Surveillance Data Collection Form. The Referral Number must be recorded at the top of each Data Collection Form. The number must be a unique identifier for the submission that will not be duplicated in any other BSE surveillance submission.

> *The Referral Number format suggested for APHIS sample collections consists of 12 alpha numeric characters (other formats that result in a unique identifier are also acceptable):*
> - First two characters indicate the State code: e.g. CO (Colorado), or WA (Washington)
> - Second three characters are the collector's initials: First, Middle, Last (if no middle name, skip middle digit)
> - Next six characters are the collection date: MMDDYY: e.g. 080704 (August 7, 2004)

- Last character is a letter representing which submission form of the day it is for the collector: A-First, B- Second, etc.

Example 1. COSAJ060104A
Translates to: Colorado – Steven Allen Jones – June 1, 2004 – first submission of the day.
Example 2. COSAJ060104B
Second submission by Steven Allen Jones for that day from that collection site.

The Referral Number for FSIS sample collections should be in the following format:
- First set of up to five characters are the FSIS Establishment Number (do not include preceding zeros or following letters; e.g., 00245 M is just "245")
- Second three characters are the collector initials: First, Middle, Last (if no middle name, skip middle digit)
- Next six characters are the submission date: MMDDYY
- Last character is a letter representing which submission of the day it is for the collector: A-First, B- Second, etc.

Example. 477CSH080404A
Translates to: FSIS Establishment 00477 – Charles Scott Henry – August 4, 2004 – first submission of day.

Collection Site: Ensure that the National Premises ID (if available for the Collection Site) is entered, or the FSIS Establishment Number where the sample was collected. Enter all the requested data for the collection site. If samples are collected from more than one site, a separate submission form must be used for each collection.

Slaughter Site: Mark the box if the slaughter site is the same as the collection site; otherwise be sure to enter all the requested information on the slaughter site. Be sure to enter the FSIS Establishment Number or the National Premises ID (if available). Leave this section blank for non-slaughter animal samples. (Note: The title line is shaded gray because the slaughter site information is not required if it is the same as the collection site. Check the box, if the information is the same.)

Collected By: Enter all of the information requested for the person that actually collected the sample. A separate submission form must be used for each collector.

Submitted By: Enter requested information for the person submitting the sample to the laboratory (the submitter) only if that submitter is a different person than the sample collector. If they are the same person, just check the box. (Note: The title line is shaded gray because the "submitted by" information is not required if it is the same as the information recorded in the collected by box.)

Sample Information: Enter the total number of samples that are included with the submission in the appropriate space. In addition, indicate how those samples are going to be preserved for shipping.

Attach a sample ID bar code label for each sample submitted with this form. If bar codes are not used, record sample ID numbers in sequential order including the BSE referral number as the first component of the Sample ID (e.g., COSAJ060104A001 or COSAJ060104A002). A USDA BSE Surveillance Data Collection Form must be attached for each sample (one per animal). Be sure to record the referral number and sample ID number on each attached data collection form. Use the "USDA BSE Surveillance Submission Continuation Form" if there are more than 20 samples included with the submission.

Collection Date: Date the samples were collected. All samples on one form must be collected on the same day. (MM/DD/YYYY format)

Shipping Date: Date the samples were shipped (submitted) to the laboratory. (MM/DD/YYYY format)

Testing Lab: Enter the name of the Laboratory (or Laboratory ID) where the samples are being sent for diagnostic testing.

Signature of Submitter: Submitter must sign the form.

Condition: For lab use only.

Distribution: For lab use only.

Received By: For lab use only.

Received Date: For lab use only.

Airbill / Shipment Tracking No.: For lab use only.

III. Completion of the paper "USDA BSE Surveillance Data Collection Form"
NOTE: A separate data collection form must be completed for each sample collected.

Date: The date the sample was collected. This date should match collection date on the submission form. (MM/DD/YYYY)

BSE Referral Number: Enter the referral number from the BSE Surveillance Submission Form which must accompany this data collection form. In the future there may be bar code labels generated for referral numbers; if available, they would be attached in this block.

BSE Sample ID: Place the bar code provided with sample kit or enter the sample ID number referenced on the accompanying BSE Surveillance Submission Form. If no bar code is available, use the following numbering scheme provided for the BSE Surveillance Information System Program. The sample ID number format is the referral number followed by 001, 002, etc.

Examples: COSAJ060104A001
COSAJ060104A002

477CSHS080404A001

Primary Reason for Submission: Use professional judgment to select the one choice that best describes the primary reason this sample is being taken.

Select "Highly suspicious for BSE (as described in VS Memo 580.16)" if the animal being sampled is demonstrating clinical signs of or has a clinical history consistent with the definition of "highly suspicious for BSE" as described in VS Memo 580.16 that is indicative of BSE. This type of sample should be submitted as a Foreign Animal Disease (FAD) investigation directly to NVSL according to the FAD submission guidelines.

Select "Nonambulatory / disabled (Downer)" if the animal is being sampled primarily because it is nonambulatory periodically or continuously.

Select "Dead" if the available history only indicates that the animal is dead with none of the preceding conditions as described above.

Select "CNS signs" if the animal is being sampled because it has demonstrated central nervous system signs.

Select "Other clinical signs that may be associated with BSE" if the animal is being sampled because it has demonstrated clinical signs that may be consistent with BSE such as emaciation, tetanus (tetany), or injuries.

Select "Rabies suspect" for all animals that were initially identified for testing for rabies because of clinical signs or clinical history.

Select "FSIS – Antemortem condemned at slaughter" for animals that are condemned by FSIS personnel prior to slaughter and are sampled at the slaughter plant or after being sent to a collection facility.

Select "Apparently healthy adult animal at slaughter" if the animal is chosen to be sampled according to the guidelines of the apparently healthy animal surveillance program. (Note – if this reason for submission is checked, the only Clinical Sign that should be and must be checked is the box labeled "Apparently Healthy Adult at Slaughter".

Owner or Source Information: Enter the National Premises ID for the premises on which the sampled animal was last held or resided, if available. Otherwise, enter as much of the requested information as is known.

Animal Information: Enter all information as requested.
- Examine the animal's mouth to determine if the 2nd incisor has erupted, if so, check "Yes" box.
- Enter the animal's age as the number of months or the number of years (in whole numbers only). For instance, if the animal is 2 ½ years old, enter 30 months. If purebred records or other official sources of age are used as the source of the animal's age, check the "Recorded" box. Otherwise indicate that the age was estimated by checking the "Estimated" box.

Country of Origin: If it is known that the animal originated from a country other than the United States of America, write the name of the country in the space provided.

Animal ID Information: In the appropriate boxes, enter all of the ID that the animal has. If the animal has more than one Official Silver Tag, include up to two in the appropriate box and include any additional tags in the Other ID boxes. Be sure to include the FSIS Condemnation

Tag # if available. The recording of the animal ID should be in accordance with the SOP for Animal Identification Recording. If the animal is branded with either a "Hot Iron Brand" or "Freeze Brand" describe to the best of your ability, for example, "Circle Bar T" in the appropriate box.

Breed: Enter the apparent breed of the animal. If "Other" is checked, fill in the breed in the provided space.

Clinical Signs: Enter at least one clinical sign, even if it is "Unknown." Use professional judgment in box selection and ensure that contradictory signs are not checked. If "Other" is checked, be sure to indicate the clinical sign in the "Comments" section at bottom of page. The box for "Apparently Healthy Adult at Slaughter" should only be checked if the Primary Reason for Submission was selected to be "Apparently Healthy Adult at Slaughter".

FSIS Condemnation Codes: Enter the appropriate antemortem condemnation code – one box must be checked if the animal is condemned by FSIS.

IV. Comparison of differences between the current BSE web-based data entry screens and the revised BSE submission and data collection forms

Some known discrepancies exist between the current submission and data collection forms and the existing data entry screens in the web-based BSE Surveillance Information System, however, it is important to begin using the revised forms as soon as possible even though the changes to the data entry screens and the data base will require additional time to effect.

Because collector information is no longer required on the supplemental form, IT IS ESSENTIAL TO VERIFY THAT A REFERRAL NUMBER AND DATE ARE PRESENT AND LEGIBLE ON ALL DATA COLLECTION FORMS.

Filling out the 10-4 Submission Online Form

Note: The numbers below correspond to data entry blocks on the Web-based data entry screens. It is assumed that the person performing the following data entry is already familiar with use of the online forms.

1. Name of Submitter – This should be the submitters name as noted on the "Submitted By" box on the BSE Surveillance Submission Form. Select from the drop down box during data entry into the online system.

3. Location of Animals – This information should be entered as noted in the "Collection Site" box on the paper BSE Surveillance Submission Form.

5, 6, 7. Unavailable on current paper form, and can be skipped when entering data on the Web forms.

8. Examination Requested – Enter "BSE Surveillance Testing."

9. Collected by – Enter name and other information for the person physically collecting the sample as noted in the "Collected By" box on the paper submission form.

10. Date Collected – Enter the date as noted on the bottom of the submission form in the "Collection Date" box.

11. Authorized by – Applicable state AVIC will be automatically filled in by the Web form.

12. Purpose of Submission –.Select "Surveillance" unless the animal was sampled because it was a BSE Suspect (as indicated in the Primary Reason for Submission); in which case chose "FAD/EP Diagnostic."

14. Referral Number – Enter the "BSE Referral Number" from the submission form. This number is also used to associate the sample IDs in section 20 (see below) to each supplemental form. Ensure that the Referral Number is recorded on each attached paper data collection form.

15. Preservation Method – Record information as indicated in the Sample Information line of the submission form.

16. Specimens Submitted – Select the box labeled "Tissue."

17. Total Number of Specimens Submitted – There is no limit to the number of samples which may be submitted using one BSE referral number. For each sample, a separate "USDA BSE Surveillance Data Collection Form" is required. Please ensure that the number of collection forms submitted match the number of samples listed on the submission form.

18. Species or Source – "Select "Bovine" from the drop down box.

19. Total Number of Subjects Sampled – Automatically filled in as samples are entered into the online form.

20. Identification – This is where sample ID information for each sample included in the submission will be entered. At least one Sample must be entered for each submission. Enter information for each sample on a separate 10-4 Supplemental Form screen by clicking the "Add Sample" button.

Filling out the 10-4 Supplemental Online Form

State, Date, and Collector - Information is entered automatically.

BSE Sample # - Enter the BSE Sample ID as noted on the BSE Surveillance Data Collection Form.

Owner or Source Information – Enter the National Premises ID, if provided on the form, and all information about the owner or source as noted in the Owner or Source Information box on the data collection form. If only partial information is known, select the "Unknown" box, then

enter all information that is known in the fields provided (partial information can only be entered if the "Unknown" box is checked). If there is no owner information available, the "Unknown" box must be checked.

Animal Information – Select "Add Animal ID" button. When pop up box appears, enter all of the animal ID information provided. If an "Official Silver Tag, Official Vaccination Tag, or Official Bangle Tag" is provided, the "ID Type" selected from the drop down list should be "Official ID". If either "Hot Iron Brand" or "Freeze Brand" is provided, the "ID Type" selected from the drop down list should be "Brand". "Collection Site Tracking Number and Slaughter Tracking Number" can not be entered as an Animal ID type at this time and if provided should be entered as a "Comment" at the bottom of the *10-4 Supplemental Online Form.*

NOTE: Animal ID entries are limited to 15 alphanumeric characters – entering more than 15 characters will result in a database error!

After entering each provided Animal ID's, click Submit. When all ID's are entered, enter the sex, age and breed of the animal as recorded on the data collection form.

Sex – If the data collection form indicates that the animal is a neutered male, it should be entered as a "Castrated Male" on the Web form. Likewise, if a neutered female is indicated, it should be entered as a "Spayed Female".

Age – The collectors are now being required to record the age of the animal in either months or years. Select the appropriate age range to accommodate the age indicated.

Breed – Select the indicated breed from the drop down list provided.

CNS Clinical Signs and Clinical Signs – The paper data collection form combines these signs into a box called "Clinical Signs." Please transfer them into the appropriate boxes on the online submission form.

Condemnation Codes – Enter FSIS Condemnation Codes (if applicable) from box on bottom of paper data submission form.

Categories – The information to fill in the "On Farm" drop down box or the adjacent "Other" drop down box can be obtained by combining the information available in the "Collection Site Type" in the upper left hand corner of the BSE Surveillance Submission Form and from the "Primary Reason for Submission" field at the top of the BSE Surveillance Data Collection Form.

Repeat the steps for this section listed above for each separate USDA BSE Surveillance Data Collection Form. Press "Submit" when all sample information is entered. Verify that each sample added is included in item **20. Identification,** when returning to the online 10-4 submission form prior to pressing "Submit" to submit that form to the BSE Surveillance Information System.

Attachment A: USDA BSE Surveillance Submission Form

USDA BSE SURVEILLANCE SUBMISSION FORM Page of

COLLECTION SITE TYPE

- ☐ Slaughter Plant ☐ Diagnostic Lab
- ☐ Renderer ☐ 3D-4D
- ☐ On Farm
- ☐ Public Health Lab
- ☐ Other: _____

Reserve for Testing Laboratory Accession or Identification Number

BSE Referral Number:

COLLECTION SITE			SLAUGHTER SITE or ✓ if ☐ Same as Collection Site		
PREMISES ID	or FSIS Plant #		PREMISES ID	or FSIS Plant #	
Name:			Name:		
Street:			Street:		
City:	State:	Zip:	City:	State:	Zip:
County:			County:		
Phone:	Fax:		Phone:	Fax:	
E-Mail:			E-Mail:		
COLLECTED BY			**SUBMITTED BY or ✓ if ☐ Same as Collected By**		
Name:			Name:		
Street:			Street:		
City:	State:	Zip:	City:	State:	Zip:
Phone:	Fax:		Phone:	Fax:	
E-Mail:			E-Mail:		

Please use a separate submission form for each collector and collection date. Attach a separate Bar Code Sticker (if available) for each sample in the spaces below. Sample ID's must match Sample ID's on BSE Surveillance Data Collection Forms. Attach a separate BSE Surveillance Data Collection Form for each animal.

SAMPLE INFORMATION NUMBER OF SAMPLES: _____ PRESERVATION: ☐ Ice Pack ☐ Other _____

BSE Sample ID	BSE Sample ID	BSE Sample ID	BSE Sample ID
BSE Sample ID	BSE Sample ID	BSE Sample ID	BSE Sample ID
BSE Sample ID	BSE Sample ID	BSE Sample ID	BSE Sample ID
BSE Sample ID	BSE Sample ID	BSE Sample ID	BSE Sample ID
BSE Sample ID	BSE Sample ID	BSE Sample ID	BSE Sample ID

ADDITIONAL DATA (attach additional page(s) if needed)

COLLECTION Date:	TESTING LAB:	SIGNATURE OF SUBMITTER:
SHIPPING Date:		

CONDITION:	DISTRIBUTION:	RECEIVED BY:	RECEIVED DATE:	AIRBILL / SHIPMENT TRACKING NO.:
Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only	Lab Use Only

Revision 08/12/04

Attachment B: USDA BSE Surveillance Data Collection Form

USDA BSE Surveillance Data Collection Form | **Date:**

BSE Referral Number:
Please Use Bar code if Available

BSE Sample ID:
Please Use Bar code if Available

PRIMARY REASON FOR SUBMISSION (Select One)

- ☐ Highly suspicious for BSE (as described in VS Memo 580.16)
- ☐ Nonambulatory / disabled (Downer)
- ☐ Dead
- ☐ CNS signs
- ☐ Other clinical signs that may be associated with BSE
- ☐ Rabies suspect

- ☐ FSIS – Antemortem condemned at slaughter
- ☐ Apparently healthy adult at slaughter

Owner or Source Information	Animal Information
Premises ID:	Gender: ☐ Female ☐ Male
Name:	Neutered: ☐ Yes ☐ No ☐ Unknown
Street:	Dentition 2nd Incisor Erupted: ☐ Yes ☐ No
City: State: Zip:	Age: _____ ☐ Years ☐ Months ☐ Estimated ☐ Recorded
County: Country:	
Phone: Fax:	Country of Origin (Only if KNOWN to be other than USA): _____
E-mail:	

Official Silver Tag#	Official Vaccination Tag#	Official Bangle Tag#	Condemnation Tag#	Back Tag#
Owner Ear Tag#	Collection Site Tracking#	Slaughter Tracking#	Hot Iron Brand	Freeze Brand
Ear Tattoo	Microchip/Electronic ID	Other ID Type:_____	Other ID Type:_____	Other ID Type:_____

Breed (Select one)

					List Breed if Other:
☐ Angus	☐ Chianina	☐ Jersey	☐ Polled Shorthorn	☐ Other Beef:	_____
☐ Brahman	☐ Galloway	☐ Limousin	☐ Red Angus	☐ Other Dairy:	_____
☐ Brangus	☐ Guernsey	☐ Maine-Anjou	☐ Santa Gertrudis	☐ Crossbred Beef	
☐ Brown Swiss	☐ Hereford	☐ Milking Shorthorn	☐ Shorthorn	☐ Crossbred Dairy	
☐ Charolais	☐ Holstein	☐ Polled Hereford	☐ Simmental	☐ Unknown	

Clinical Signs (Select all that apply, at least one)

☐ Abnormal Gait	☐ Convulsions / Seizures	☐ Head Pressing (against object)	☐ Sensitive to Light
☐ Aggressive	☐ Dead – Unknown Cause	☐ Head Tremors	☐ Shifting Ears
☐ Apprehension / Nervous	☐ Decreased Milk Yield	☐ Injuries (poss. CNS related)	☐ Stupor
☐ Ataxia (uncoordinated)	☐ Depressed	☐ Licking Muzzle	☐ Tetany
☐ Belligerent	☐ Down (describe in comments)	☐ Nystagmus (eye movements)	☐ Tremors
☐ Blindness	☐ Droopy Lip or Eyelid	☐ Off Feed	☐ Thin (underweight)
☐ Bug Eyed (bulging eyeballs)	☐ Excessive Bellowing	☐ On Side (head back, paddling)	☐ Weak / rigid or relaxed
☐ Circling	☐ Frenzy / Hysteria / Mania	☐ Overly Excitable	☐ Other (describe in comments)
☐ Coma (unconscious)	☐ Grinding Teeth	☐ Paralyzed / rigid or relaxed	☐ Apparently Healthy Adult at Slaughter
		Pupils: ☐ Dilated ☐ Pinpoint	

FSIS Condemnation Codes (Select one – ONLY if FSIS has made one of these designations)

☐ Degen & Dropsic	099	☐ Misc. inflamm dz.	299	☐ Injuries	605	☐ Tetanus	105
☐ Actinomycosis & Acitinobacillosis	101	☐ Epithelioma	302	☐ Pigment conditions	607	☐ Vesicular dz.	110
☐ Misc. infectious dz.	199	☐ Malig lymphoma	303	☐ Myiasis	402	☐ CNS disorders	601
☐ Arthritis	201	☐ Misc. neoplasms	399	☐ General misc.	699	☐ Dead	603
☐ Mastitis	203	☐ Abscess/pyemia	501	☐ Residue	609	☐ Moribund	606
☐ Metritis	204	☐ Septicemia	502	☐ Other reportable dz.	900	☐ Pyrexia	608
☐ Pericarditis	206	☐ Toxemia	503	☐ Misc. parasitic cond.	499	☐ Rabies	615
☐ Pneumonia	208	☐ Nonambulatory	445				

Comments:

Revision 08/12/2004

Quick Start Guide - BSE Lab Submission Webpage

Website address for accessing the BSE Lab Submission Webpage:
https://nahln.aphis.usda.gov/nahln/jsp/login.jsp

Quick Overview

The USDA is initiating a surveillance program to determine if any evidence of bovine spongiform encephalopathy (BSE) exists in the U.S. cattle population. Private practitioners, along with rendering plant, slaughter plant, industry, university, federal and state personnel are assisting with this effort.

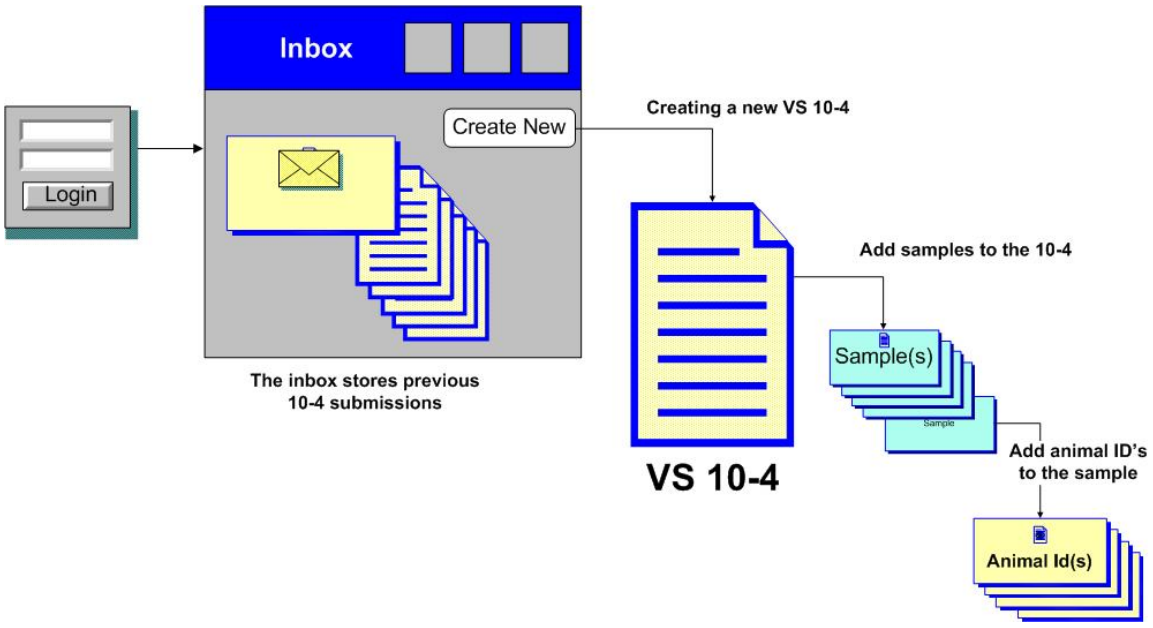
Appropriate tissue samples from cattle will be collected by the authorized personnel and submitted to pre-designated animal disease diagnostic laboratories. The samples will be tested with a rapid screening test and the submitters (personnel who sent the sample to the laboratory) will be notified of the result. The USDA APHIS VS Area Veterinarian-in-Charge of the State where the sample was collected will also be notified of the results.

In order for the surveillance program to be successful, key information needs to be entered at the time that the sample is collected and when the sample has been tested. There will be two methods for entering this information – via the BSE Lab Submission Webpage and also via tablet PCs at high-volume collection sites.

This Quick Start Guide provides directions for the use of the BSE Lab Submission Webpage; additional documentation will be distributed with the tablet PCs.

The BSE Lab Submission Webpage is used for entering and transmitting data from a handwritten USDA BSE Surveillance Submission Form. After entering and submitting the information, the data are then stored in the National Animal Health Laboratory Network (NAHLN) in order to correlate the test results with the appropriate samples collected.

Pictorial Overview of the BSE Lab Submission Webpage



Steps to Creating a New Lab Submission:

Steps	Details
1. CREATE NEW VS 10-4	Information is filled out on the "VS 10-4" Webpage form. Fields marked with an asterisk (*) are required fields.
2. ADD SAMPLES	A secondary Web form, the "10-4 Supplemental," is used to add Animal Sample(s) to the electronic 10-4. At least one sample must be added to each 10-4. Multiple samples can be attached to one form. In fact, there is no limit to the number of samples that can be attached to one VS 10-4.
3. ADD ANIMAL ID'S	A third Web form is used to associate Animal ID(s) (i.e., ear tag, tattoo, etc.) with each sample. At least one animal ID must be added to each sample. If an animal possessed more than one animal ID, then multiple ID's can be added to each individual sample as well.
4. SUBMIT TO LAB	The completed 10-4 form is submitted. This transmits the information to the selected lab. If you are not able to complete the form at this time, it can be saved to the Inbox to be completed and submitted at a future time.
5. SHIP/NOTIFY LAB	A copy of the paper BSE Surveillance Submission Form is included with the shipment of samples and the lab is notified (by phone, email, fax, etc.) that the samples are being shipped. The following day, the submitter should verify through the overnight carrier that the shipment arrived.

What Role am I?

Since users of the BSE Lab Submission Webpage perform different tasks, they are granted different capabilities (roles) with respect to the information that is collected through the BSE Lab Submission Webpage.

The role that you have been granted is dependent on your job role. Examples of different roles are AVIC, Epidemiologist, Data Entry Clerk, Submitter, Lab Technician etc. The username that you use to log on to the system controls the type of role that you have. For instance, a Data Entry Clerk at a certain location can enter, modify and delete all information pertaining to samples that have been entered and submitted by her; but she cannot access or review information regarding samples collected at another location. A Laboratory Technician can enter the test results for samples that have been sent to her lab for testing, but cannot modify any of the previous information regarding that sample. An AVIC can view information on samples collected in her State or originating from her State, but she cannot modify the information or view samples originating from other states, unless she is responsible for those states.

Username and passwords for the BSE Lab Submission Webpage are completely separate of any other usernames and passwords that you may have. In other words, the username/password that you use to log on to your computer, Lotus Notes, GDB or any other system has no relationship to your login for the BSE Lab Submission Webpage.

For more detailed information regarding roles and their privileges, please consult Attachment C in this Appendix.

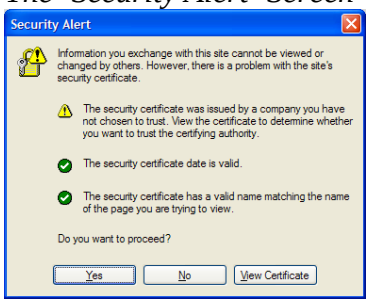
Logging In

To begin entering information on the BSE Lab Submission Webpage, use your Web browser to connect to the following page:

https://nahln.aphis.usda.gov/nahln/jsp/login.jsp

You will know that you are at the correct location if you see the following screen:

The 'Security Alert' Screen

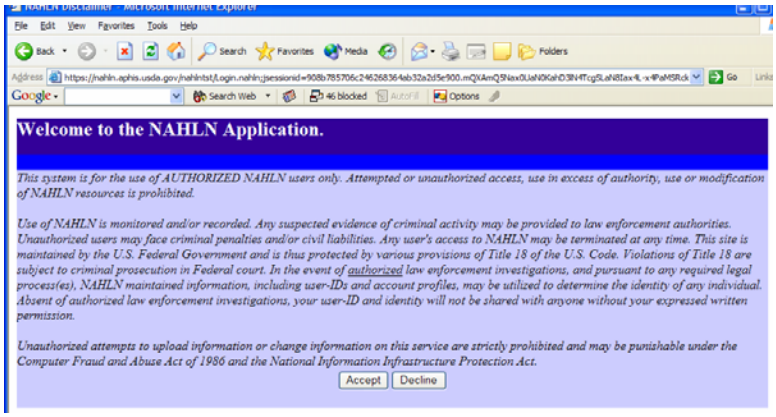


Click '**Yes**' to proceed to the next screen – the "NAHLN Login" screen.

The 'NAHLN Login' Screen

Type in the User Name and Password that have been assigned to you. The User Name and Password are case-sensitive – meaning you need to enter uppercase (capital) or lowercase letters exactly as they appear in your assigned User Name and Password. After successfully entering your User Name and Password, you will be presented with the "NAHLN Welcome" screen.

The 'NAHLN Welcome' Screen

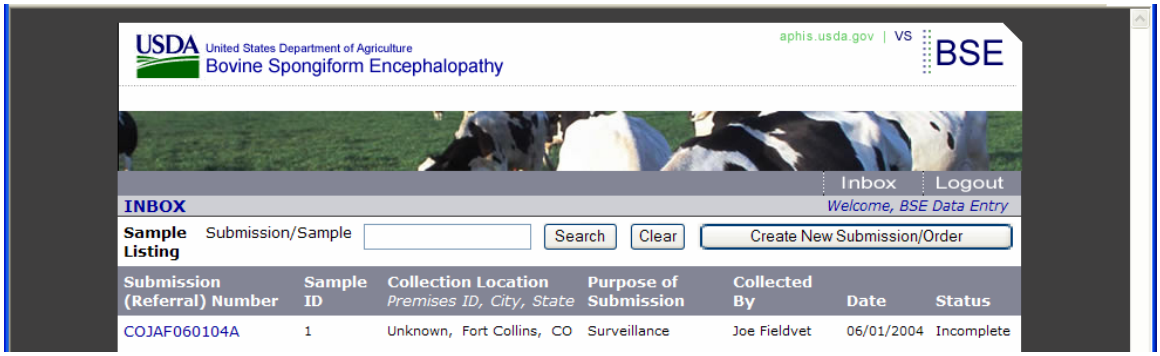


Please read the conditions for use of the NAHLN system; then click '**Accept**' to proceed. f you decline the terms of use, you are not allowed further into the NAHLN Application.

If you accept the conditions you will proceed to the next screen – the "BSE Inbox" screen.

The BSE Inbox

The 'Inbox' Screen



If this is the first time that you are in your inbox, you will see the message 'No submissions found'. Once you have entered and saved or submitted information, the submission numbers, and other key information, from all of your previously entered data will be displayed (as shown above). At this point, you can view previously entered information, modify existing information, or enter a new submission.

In the screen above there is one submission (COJAF060104A) already listed. Clicking on this number will allow you to view, or edit that submission. You may edit any submissions that you have previously 'Saved'. You can only view submissions which have already been 'Submitted' to a lab.

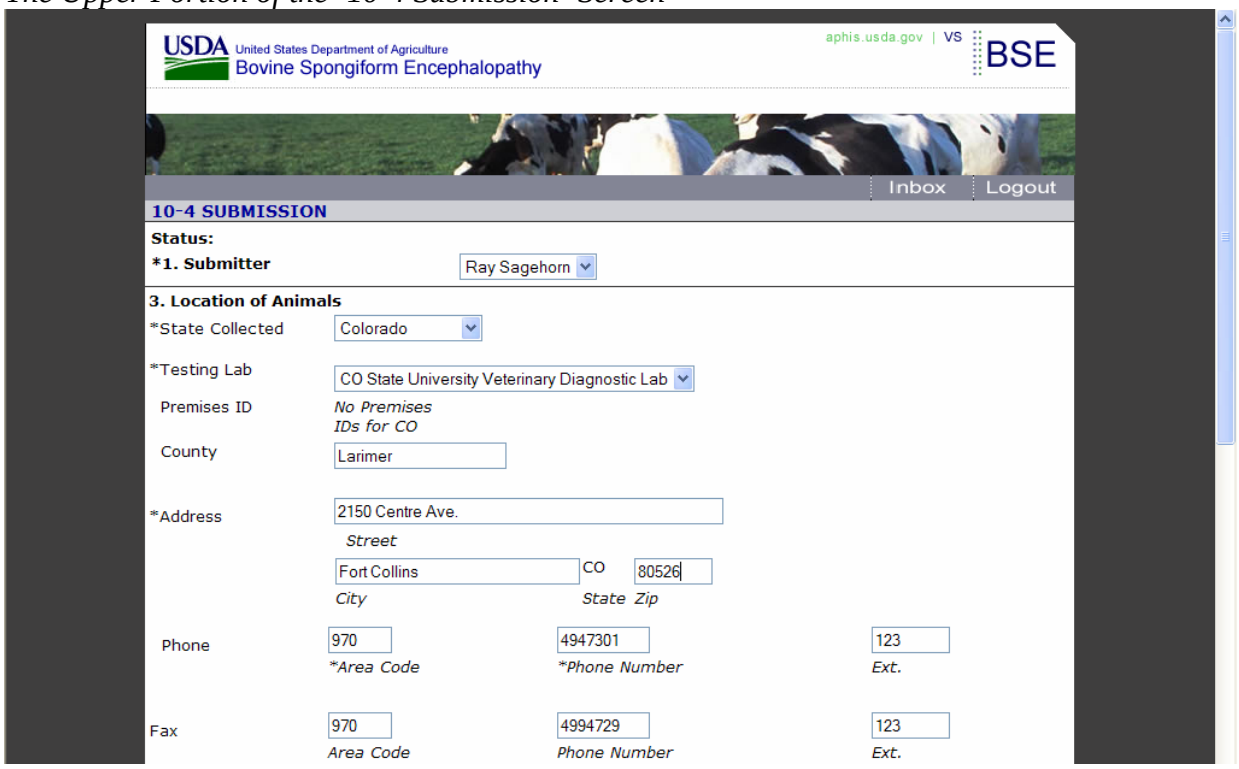
Alternatively, you may choose to create a new Submission/Order. Other functions that you can perform at this time are identified in the table below:

Guide to the 'Inbox Screen'

Field	Purpose
Submission/Sample	Input search criteria. You may use the % sign as a wildcard. For example, %WE% would find 'WEST' as well as 'KOWE'. In addition, searches are case-sensitive, %WE% will not find 'kowe'.
Buttons	**Action Performed**
Search	Clicking on this button will search for any submission or sample numbers in your Inbox using whatever criteria you have typed into the 'Submission/Sample' field (which can be found to the left of the 'Search' button).
Clear	Clears the Submission/Sample field to permit a new search.
Create New Submission/Order	Clicking on this button will begin the process of creating a new electronic VS 10-4.
Links	**Link Destination**
Inbox	Clicking on this link always returns you to your Inbox. Since you are currently in your inbox, it will have no effect.
Logout	Clicking on Logout will log you out of the BSE Lab Submission Webpage.
Links at bottom of page	Clicking on these links, (i.e., 'Home', 'About USDA', etc.) will take you to the indicated destination. The site will open in a new browser window.

Creating a Sample Submission

The Upper Portion of the '10-4 Submission' Screen



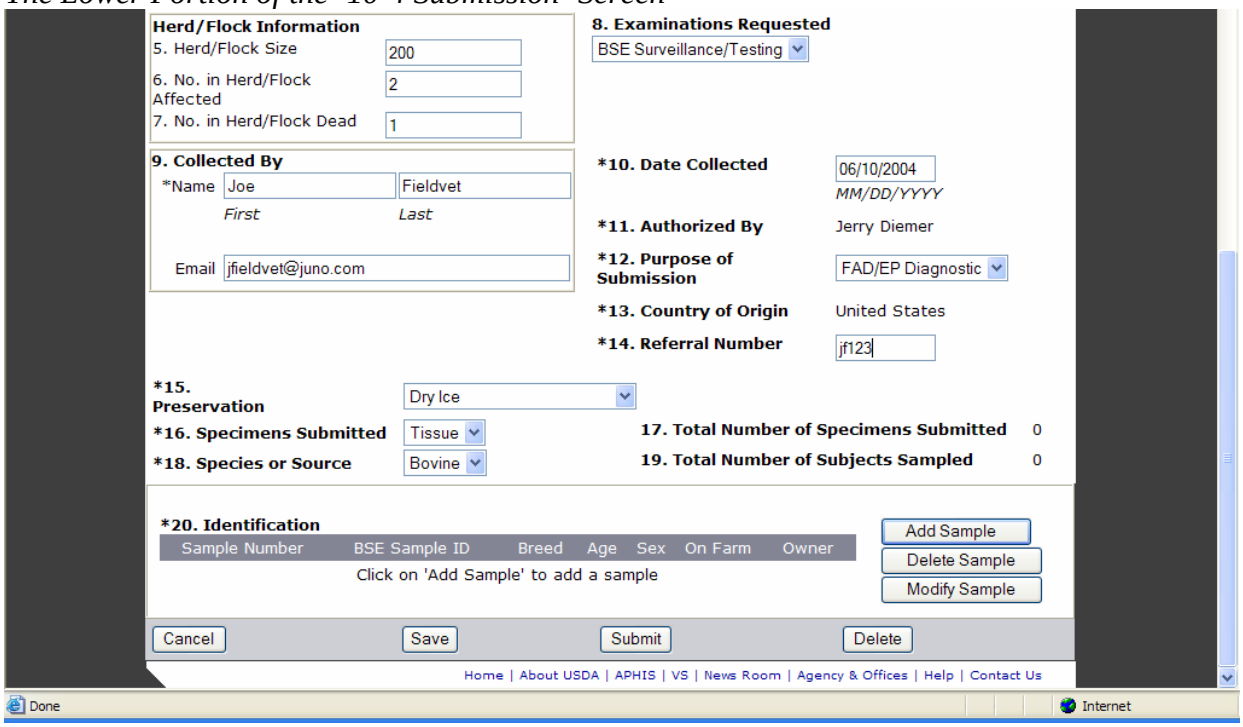
Note: Fields preceded by an asterisk (*) are required fields.

Field	Purpose
*1. Submitter	The name of the person who will actually be submitting this form to the appropriate laboratory. This would be the field vet, private practitioner, or contractor who has been authorized to collect and submit BSE samples.
2. Name of Owner	This does not appear on this portion of the form. You will be prompted for it later when you add a sample to this submission.
3. Location of Animals *State Collected	The state from which the animal submission was collected. Select from the drop-down list.
*Testing Lab	This field will be filled in automatically after a state is selected.
Premises ID	The national premises ID from which the animal submission was collected.
County	The county from which the animal submission was collected.
*Address City State Zip	The city from which the animal submission was collected. This field will be filled in automatically based on your input in the 'State Collected' field. The five-digit zip code of the location from which the animal submission was collected.
Phone * Area Code * Phone Number Ext.	Three-digit area code Seven-digit phone number. Do not add a space or hyphen separator. Multiple digit or character extension.
Fax Area Code Phone Number Ext.	Three-digit area code for fax Seven-digit phone number for fax. Do not add a space or hyphen separator. Alphanumeric phone extension.

Links	Link destination
Inbox	Clicking on this link always returns you to your Inbox. You will receive the following message: "*If you return to the Inbox now, you will lose any changes you may have made. Are you sure you want to do this?*" You should save or submit your electronic 10-4 or else you will lose the information on the current 10-4 form if it has not been previously saved.

Logout	Clicking on Logout will log you out of the BSE Lab Submission Webpage. You should save or submit your electronic 10-4 or else you will lose the information on the current 10-4 form (if it has not been previously saved).

The Lower Portion of the '10-4 Submission' Screen



Use the scroll bar (on the right hand side) to view the lower portion of the 10-4 screen.

Field	Purpose
Herd/Flock Information 5. Herd/Flock Size	Number of cattle in herd where cow was at time of sampling.
6. No. in Herd/Flock Affected	Number of cattle in the same herd showing any CNS signs.
7. No. in Herd/Flock Dead	Number of cattle in same herd that have died within the last month.
8. Examination Requested	BSE Surveillance/Testing is automatically selected.
9. Collected by: *Name: First Last	First name of the person who physically collected the specimen. Last name of the person who physically collected the specimen.
Email	Email address of the person who physically collected the specimen.
*10. Date Collected	The date that the sample was physically collected.
*11. Authorized By	State AVIC. This field is automatically filled in.
*12. Purpose of Submission	Select either "FAD/EP diagnostic" or "Surveillance, depending if the sample was collected due to a FAD investigation or for BSE surveillance purposes.
13. Country of Origin	Not applicable ("United States" is a default).
*14. Submission (Referral) Number	This is a number entered by the submitter using the following format: 2 character State Code, 3 character submitter initials, 6 digit date (mmddyy), 1 or 2 digit sequential character. Example 1: COSAJ060104A Translates to: Colorado -Steven Allen Jones - June 1, 2004 - A (the first submission of the day) Example 2: COSAJ060104B (indicates second submission [10-4] of the day)
*15. Preservation	This field describes how the sample is preserved for shipping. Select from the drop-down list.

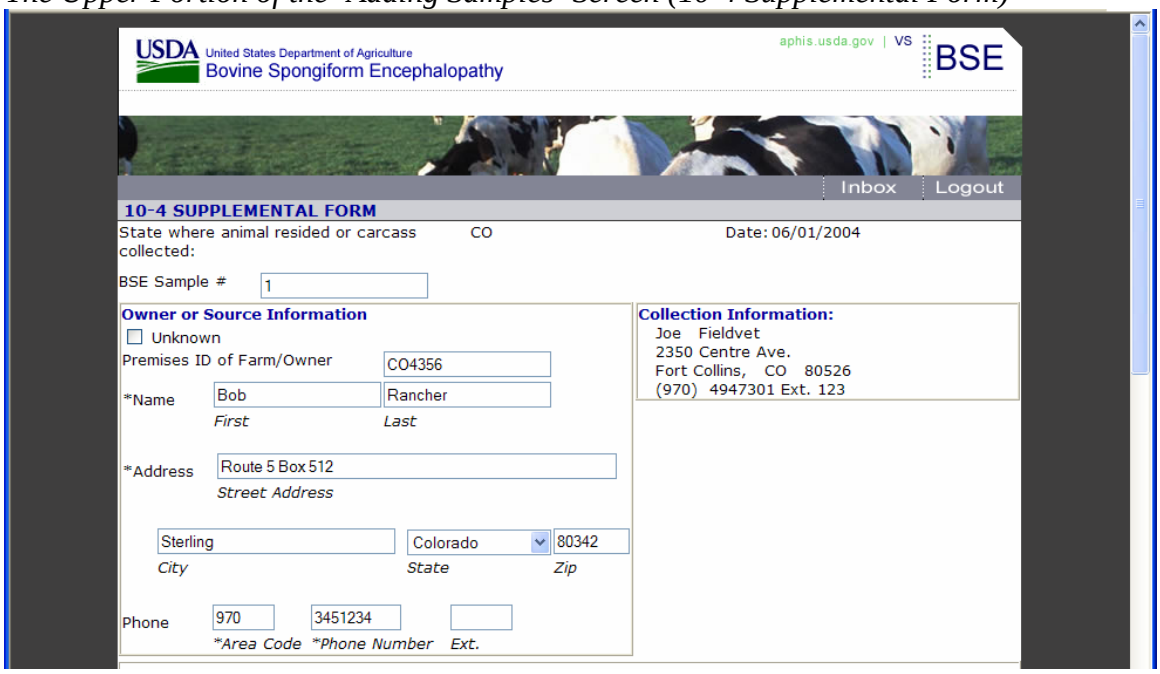
*16. Specimens Submitted	The specimen will always be 'Tissue'.
17. Total Number of Specimens Submitted	This field displays the total number of specimens submitted. There is no limit to the number of samples submitted by one form. A 10-4 continuation sheet will be automatically produced for more than 10 sample submissions. For each sample, a separate "10-4 Supplemental Form" is required.
*18. Species or Source	Accept the default of "Bovine" for cattle.
19. Total Number of Subjects Sampled	This field displays the total number of animals sampled. It is automatically filled in.
*20. Identification	This field will be blank until the 'Add Sample' button is clicked and identification is added to the samples.

Buttons	Action Performed
Add Sample	Clicking on this button will bring up a separate box allowing you to add samples. See the *"Add Sample" screen* below.
Delete Sample	If there is a sample that you have already added to this submission and you wish to delete the sample now, select the sample by clicking the radio button next to it and then click the 'Delete Sample' button. Samples can only be deleted one at a time.
Modify Sample	If there are samples that you have already added to this submission and you wish to modify them, select one of the samples by clicking the radio button next to it and then click the 'Modify Sample' button. Samples can only be modified one at a time.
Cancel	Clicking on this button will cancel the edits that you have already made and return you to the 'Inbox'. You will lose any information that you have entered on the current screen. If you have previously saved the submission, the saved version will still be intact.
Save	Clicking on this button will save your entry even if the 10-4 is incomplete. However, the laboratory will not have a record of your samples until you click 'Submit'. You can return to the 10-4 at a later time to modify, complete it and submit it.
Submit	Clicking on this button will submit your 10-4 to the laboratory. All required fields must be complete before clicking on 'Submit'. If there are required fields that are not completed, you will receive a message telling you what field(s) are incomplete and be given the opportunity to complete them. Once you submit a 10-4, you cannot edit it. Only the AVIC or Lab can modify a 10-4 after it has been submitted.
Delete	Clicking on this button will delete the 10-4 submission, even if it has been saved. You cannot delete a 10-4 that has already been submitted to the laboratory.

Links	Link Destination
Inbox	Clicking on this link always returns you to your Inbox. You will receive the following message: "*If you return to the Inbox now, you will lose any changes you may have made. Are you sure you want to do this?*" You should save or submit your electronic 10-4 or else you will lose the information on the current 10-4 form if it has not been previously saved.
Logout	Clicking on Logout will log you out of the BSE Lab Submission Webpage. You should save or submit your electronic 10-4 or else you will lose the information on the current 10-4 form (if it has not been previously saved).
Links at bottom of page	Clicking on these links, (i.e. 'Home', 'About USDA', etc.) will take you to the indicated destination. The site will open in a new browser window.

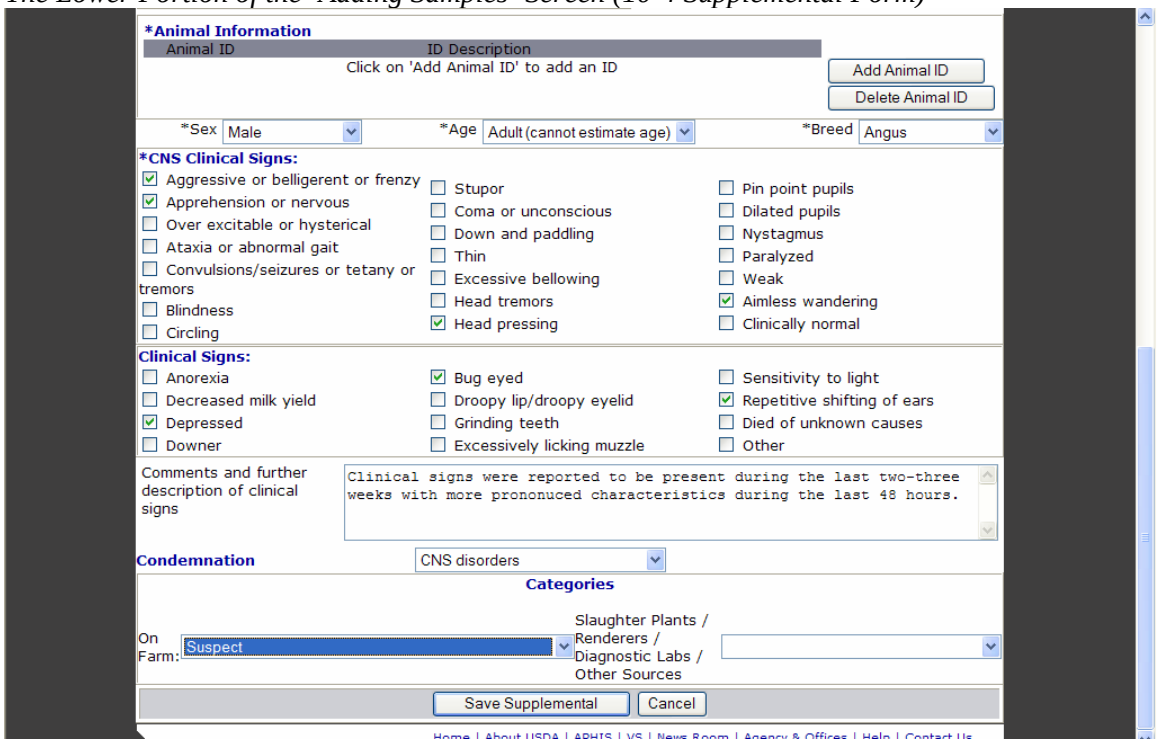
Adding Samples

The Upper Portion of the 'Adding Samples' Screen (10-4 Supplemental Form)



Field	Purpose
State where animal resided or carcass collected.	This field will be filled in automatically based on your input in the 'State Collected' field.
Date	This field will be filled in automatically with the date that the sample was physically collected.
BSE Sample #	Preferred: Use laboratory provided barcode when available. Secondary: Use number of the format "Submission (Referral) Number" + "three-digit sequential tube number". Example 1: COSAJ060104A001 (1st sample of 1st submission of June 1, 2004) Example 2: COSAJ060104B013 (13th sample of 2nd submission of June 1, 2004) Note: See Line #14 for the format of the "Submission (Referral) Number" Laboratory results will be reported by this sample identification number.
Owner or Source Information Unknown	"Owner or Source" refers to the premises on which the sampled animal was last held or was last resident. Select "Unknown" if any of the information about the last premises is not known. If partial information is known, select 'Unknown" and enter all information that is known in the fields below.
Premises ID of Farm/Owner	Self-explanatory. A future release will verify the national Premises ID against the national premID allocator.
*Name First	First name of the premises owner if known.
Last	Last name of the premises owner if known.
*Address	Street address of the premises owner if known.
City	City of the premises owner if known.
State	State of the premises owner if known.
Zip	Zip code of the premises owner if known.
Phone *Area Code Phone Number Ext.	 Three-digit area code Seven-digit phone number. Do not add a space or hyphen separator. Multiple digit or character extension.
Collector Information:	The name and address of the collector will be filled in automatically based on your previous input.

The Lower Portion of the 'Adding Samples' Screen (10-4 Supplemental Form)



Field	Purpose
*Animal Information *Sex	The sex of the animal that was sampled. Select from the drop-down list.
*Age	The age of the animal that was sampled. Select from the drop-down list.
*Breed	The breed of the animal that was sampled. Select from the drop-down list.
*CNS Clinical Signs	You are required to select one or more of these check boxes to provide information pertinent to CNS (central nervous system) clinical signs. Professional judgment should be used regarding which boxes to check. Some combinations of checkboxes could be contradictory (e.g., "over excitable" contradicts "clinically normal").
Clinical Signs:	You may select one or more of these check boxes to provide information pertinent to Clinical signs. Professional judgment should be used regarding which boxes to check. Some combinations of check boxes could be contradictory.
Comments and further description of clinical signs	Add further information or comments about clinical signs.
Condemnation	Select from the drop-down list the reason for condemnation of the affected animal.
Categories:	(Select from only <u>one</u> category box as appropriate!)
On Farm:	Select from this drop-down list if the sample was collected on a farm.
Slaughter Plants/ Renderers/ Diagnostic Labs/ Other Sources	Select from this drop-down list if the sample was collected at a slaughter plant, renderer, etc.

Buttons	Action Performed
Cancel	Clicking on this button will cancel the edits that you have already made and return you to the Inbox. You will lose any information that you have input on the current screen. If you have previously saved the submission, the saved version will still be intact.
Save Supplemental	Clicking on this button will save your work even if the submission is incomplete. You can return to the submission at a later time and modify or complete it.
Add Animal ID	Clicking on this button permits you to add an animal ID to the sample. See "Adding Animal ID's" below for details.
Delete Animal ID	If there is an animal ID that you wish to delete, select the animal ID by clicking the radio button next to it, then click the 'Delete Animal ID' button. You can only delete one animal ID at a time.

Adding Animal ID's

The 'Add Animal ID' Screen

Field	Purpose
*Animal ID:	Enter an individual Animal ID of the animal for this sample. Animal ID's can be of the type found in the 'ID Type:' drop-down list. You will be provided the opportunity to enter additional ID's, one at a time.
*ID Type:	Select the ID type of the animal for this sample from the drop-down list.
Buttons	**Action Performed**
Submit	Clicking on this button will add the Animal ID that you have entered to the current sample.
Cancel	Clicking on this button will cancel 'Adding an Animal ID' and return you to the current sample. You will lose any information that you have input on the current screen.

Congratulations, you have now entered all of the prerequisite information! You may now enter additional animal ID's for this sample.

After you return to the main form, you may then add additional samples. If you have no additional samples to enter, you may then click on 'Submit' to transmit this sample to the appropriate lab.

If you still have additional edits to make to this form, you may 'Save' the form and return to work on it at a future time. You will be able to access it from your BSE Inbox.

Printing 10-4 and Supplemental Forms

A printed copy of each 10-4 and its attached supplemental forms should be placed in the box with actual samples prior to shipping to the laboratory. At this time – just use the 'Print' button provided by your Web browser for each page. Enhanced printing capabilities will be added to the BSE Lab Submission Webpage in the near future.

Entering Laboratory Test Results

Some changes are currently being made to make it easier to enter the test results at the sample-processing laboratories. Additional documentation will be sent to these labs in the near future.

Key Points to Remember

Use the 'Cancel' button to move to a previous page once you are logged into the BSE Lab Submission Webpage. The 'Back' button in your Web browser will affect the application operation. Avoid using the 'Back' button.

Use the 'Save' button only if you want to add or modify information prior to sending the information to the NAHLN (BSE) database and subsequently to the laboratory.

Once all information has been entered for the 10-4, remember to print each page prior to pressing the 'Submit' button.

Required fields are marked with an asterisk (*) – these fields must be entered.

Troubleshooting and Support

The BSE Lab Submission Webpage validates much of the information that you enter. If you receive an error message, you can frequently determine the cause of the problem simply by carefully reading the error message that appears at the top of each screen.

For additional support please call: 1-866-370-6611 (8:00 a.m. to 5:00 p.m. Mountain Time). Please be at your computer when calling.

Attachment C: User Roles

User role	Permissions
Submitter	Submit data for your own submissions.
	View Inbox with your own submissions and test result data.
AVIC	Submit and correct data for states in your area. Add, delete or correct premises information.
	View Inbox with all submissions and test result data from your area.
	View reports based on state(s) in your area.
	Approve/deny requests for submitter access.
	Distribute test results to appropriate personnel.
National BSE Epidemiologist	View Inbox with submission and test results for all submissions by lab, state, region and national.
	View reports based on submitters, states, region and national submissions.
Regional BSE Epidemiologist	View Inbox with submission and test results for submissions by state or labs within region.
	View reports based on submitters in their region and regional reports.
State BSE Epidemiologist	Submit data for your own submissions.
	View Inbox with all submissions and test result data from your state.
	View reports based on submitters in your own state.
NVSL	Submit lab results data.
	View submissions and test results for all submissions by all laboratories.
	View reports based on individual labs' submissions and test results.
State/Contract Labs	Submit lab results data.
	View submissions and test results for submissions to your own lab.
	View reports based on submissions and test results to your own lab

Barcodes

If barcodes are available from the lab, here is how to use them:

Barcodes are printed in sets of 8 individual labels (See figure 1 below) that should be used for one animal only. If you use barcodes you MUST attach them as follows:

- 1 label on the sample tube (As shown in figure 2)
- 1 label on the USDA BSE Surveillance Data Collection form (as shown in Figure 3)
- 1 label on the plastic bag containing ID devices (tattoos, brands etc) removed from the animal that was sampled

If appropriate they should also be used as follows:

- 1 label on the USDA BSE Surveillance Submission form in the field marked "BSE Sample ID"instead of writing in 1, 2, 3 etc. as noted in the instructions. (Because of size, you may not be able to get 20 bar code labels on the USDA BSE Surveillance Submission form – use the USDA BSE Surveillance Submission Continuation form for additional animals)
- 1 each on the head and carcass (attach to a bangle tag or other labeling device)
- 2 for any other applications as needed

NOTE: Any labels that are not used should be destroyed

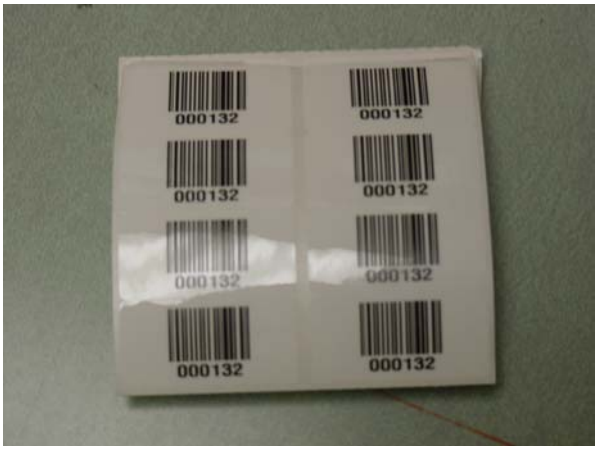


Figure 1

Figure 2

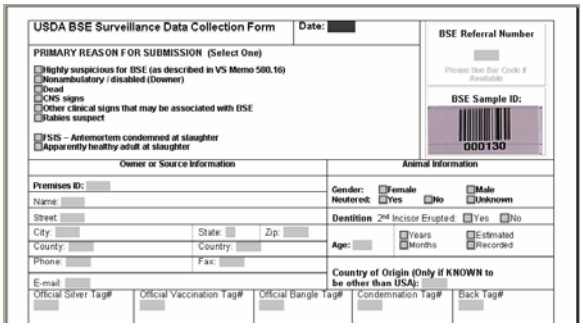
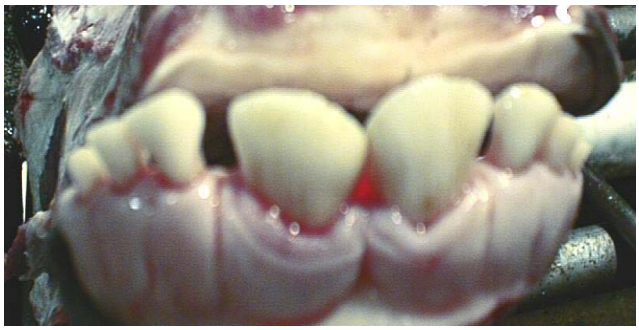
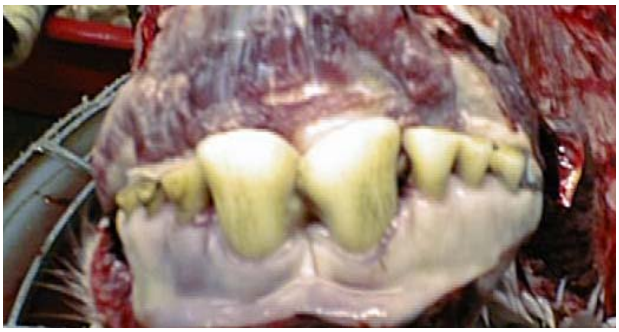


Figure 3

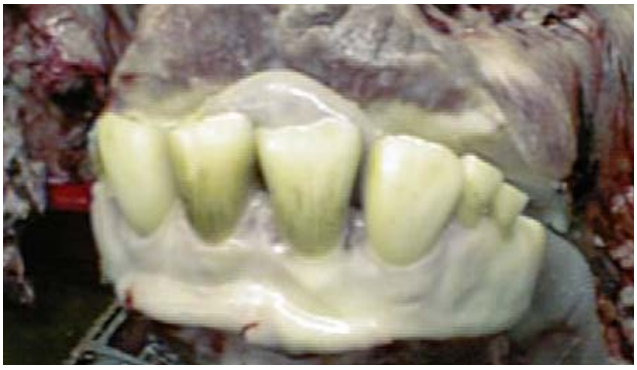
Uniform Aging for BSE Sampled Animals



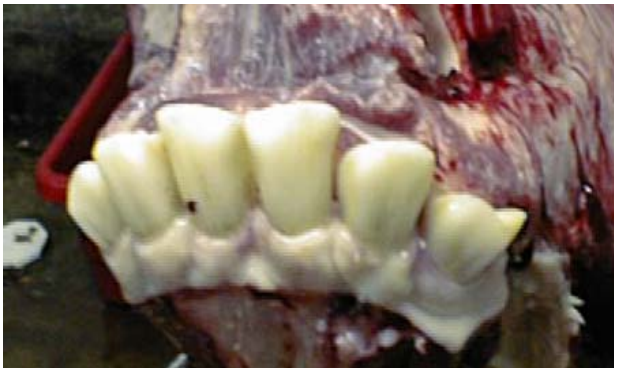
- **20 MONTHS OLD**
- Front 2 permanent incisors beginning to erupt



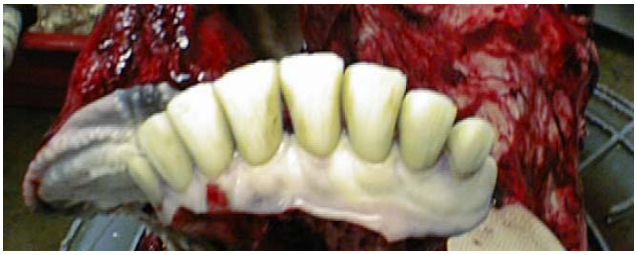
- **2 YEAR OLD**
- Two permanent incisors fully exposed
- All other teeth are still baby teeth



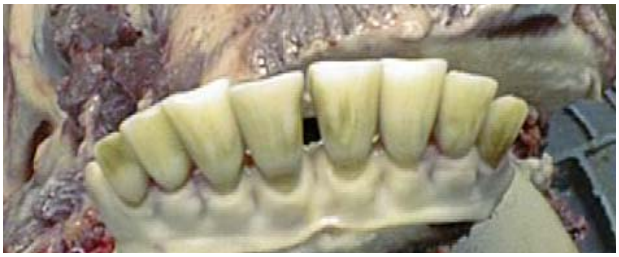
- **3 YEAR OLD**
- Four permanent incisors exposed
- All other teeth are baby teeth



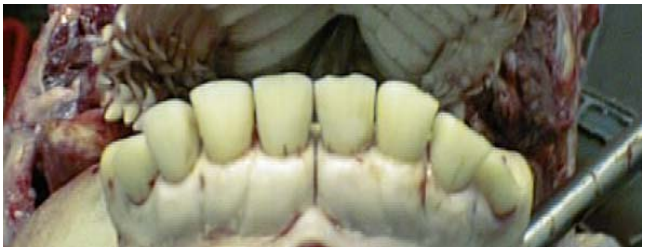
- **4 YEAR OLD**
- 6 Permanent incisors exposed



- **5 YEAR OLD**
- Eight permanent incisors exposed
- Outside incisors slightly shorter
  All teeth have good length



- **6 YEAR OLD**
- Permanent incisors are beginning to wear in length
- Gapping is more evident
- Outer incisors are almost even in length

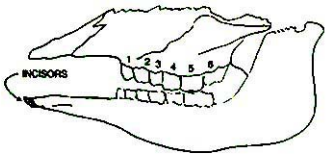


- **7 & 8 YEAR OLDS.**
- More evidence of wear on all incisors
- Shorter overall length

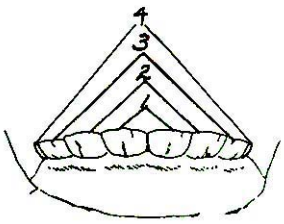
- **8+ YEAR OLDS**
- Due to the difficulty in accurately aging animals over 8 years, everything older than 7 will be called 8 years old
- Severe wear
- Possibly loose or even missing teeth
- Gapping is usually evident
- Gum recession is evident

Sketches of Uniform Aging For BSE Sampled Animals

Cattle Dental Formula. (Adapted from Bovine Practitioner, No. 9-74, and "Incisor Tooth Eruption, Development and Attrition," Texas A&M University.)

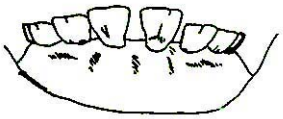


Upper and lower arcades showing premolars and molars. 1—1st premolar; 2—2d premolar; 3—3d premolar; 4—1st molar; 5—2d molar; and 6—3d molar.



18 months

19 months



20 months

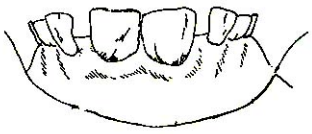
Cattle Dental Formula (continued)

20 1/2 months

21 months

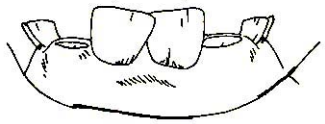
22 months

23 1/2 months

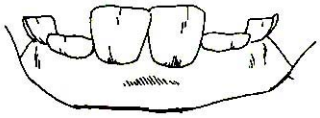


25 months

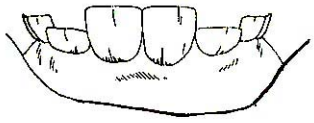
Cattle Dental Formula (continued)



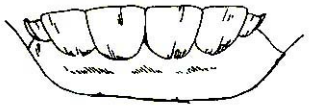
26 1/2 months



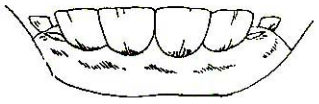
27 months



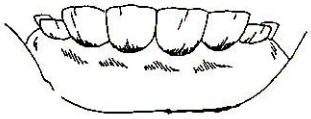
27 1/2 months



29 1/2 months

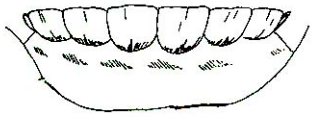


30 months

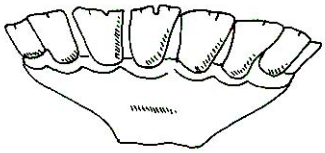


32 months

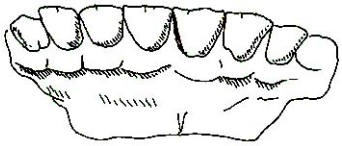
Cattle Dental Formula (continued)



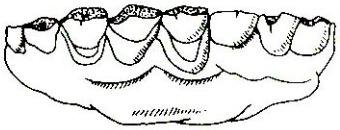
34 months



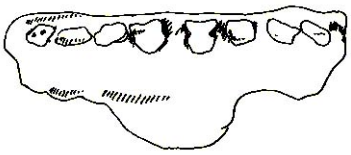
5 years



7 years



9 years



11 years

Background on BSE

Bovine spongiform encephalopathy (BSE), widely known as "mad cow disease," is a chronic, degenerative disease affecting the central nervous system of cattle. Worldwide there have been more than 180,000 cases since the disease was first diagnosed in 1986 in Great Britain. BSE has had a substantial impact on the livestock industry in the United Kingdom. The disease has also been confirmed in native-born cattle in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Israel, Italy, Japan, Luxembourg, Liechtenstein, the Netherlands, Northern Ireland, Poland, Portugal, Slovakia, Slovenia, Spain and Switzerland. However, over 95% of all BSE cases have occurred in the United Kingdom. There have been two confirmed cases of BSE in North America, both from a herd that originated in Canada. One was confirmed in May of 2003 in Alberta Canada while the other was confirmed in an animal found in Washington State in the US in December 2003.

BSE belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSE's). These diseases are caused by a transmissible agent which is yet to be fully characterized. They share the following common characteristics

a. a prolonged incubation period of months or years;
b. a progressive debilitating neurological illness which is always fatal;
c. when examined by electron microscopy, detergent treated extracts of brain tissue from animals or humans affected by these diseases reveal the presence of scrapie associated fibrils (SAF);
d. pathological changes appear to be confined to the CNS and include vacuolation, and astrocytosis;
e. the transmissible agent elicits no detectable specific immune response in the host which has inhibited the development of a preclinical live animal diagnostic test to date.

Clinical Signs of BSE in Cattle

Affected animals may display changes in temperament, such as nervousness or aggression; abnormal posture; incoordination and difficulty in rising; decreased milk production; or loss of body condition despite continued appetite. There is no treatment, and affected cattle die.

The incubation period ranges from 2 to 8 years. Following the onset of clinical signs, the animal's condition deteriorates until it dies or is destroyed. This usually takes from 2 weeks to 6 months. Most cases in Great Britain have occurred in dairy cows between 3 and 6 years of age.

How BSE Is Currently Diagnosed

There is no test to detect the disease in a live animal. Currently there are two laboratory methods to confirm a diagnosis of BSE: 1. microscopic examination of the brain tissue to identify characteristic changes; 2. techniques to detect the partially-proteinase resistant form of the prion (PrP^{res}) protein. These techniques are immunohistochemistry, immunoblotting and ELISA.

Similar Diseases of Humans and Other Animals

TSE's are caused by similar uncharacterized agents which usually produce spongiform changes in the brain. TSE's include scrapie (which affects sheep and goats), transmissible mink encephalopathy, feline spongiform encephalopathy, chronic wasting disease of deer and elk, and in humans, kuru, Classical Creutzfeld-Jakob Disease (CJD), Gerstmann- Straussler syndrome, fatal familial insomnia, and vCJD.

BSE and vCJD—Human Health Concerns

On March 20, 1996, the UK's Spongiform Encephalopathy Advisory Committee (SEAC) announced the identification of 10 cases of a new variant form of CJD (vCJD). All of the patients developed onset of illness in 1994 or 1995. The following features describe how these 10 cases differed from the sporadic form of CJD:

- The affected individuals were much younger than the classical CJD patient. Typically, CJD patients are over 63 years old. The average patient age for the onset of variant CJD was 28 (range of 12 to 74) years.
- The course of the disease in the vCJD averaged 14 months. Classical CJD cases average a 4–6 month duration.
- In the variant cases, electroencephalographic (EEG) electrical activity in the brain was not typical of classical CJD.
- Although brain pathology was recognizable as CJD, the pattern was different from sporadic CJD, with large aggregates of prion protein plaques.

Epidemiological and case studies have not revealed a common risk factor among the cases of vCJD. According to the SEAC, all victims were reported to have eaten beef or beef products in the last 10 years, but none had knowingly eaten brain material. One of the affected individuals had been a vegetarian since 1991.

The SEAC concluded that although there was no direct scientific evidence of a link between BSE and vCJD, based on current data and in the absence of any credible alternative, the most likely explanation at that time was that the cases were linked to exposure to BSE before the introduction of control measures, in particular, the specified bovine offal (SBO) ban in 1989.

Research reported in later 1996 and 1997 has found evidence to further support a causal association between vCJD and BSE. Two significant studies published in the October 2, 1997 edition of *Nature* lead the SEAC to conclude that BSE agent is highly likely to be the cause of vCJD. Dr. Moira Bruce and colleagues at the Institute for Animal Health in Edinburgh, Scotland inoculated 3 panels of inbred mice and one panel of crossbred mice with BSE, vCJD and sporadic CJD. Results indicate that mice inoculated with BSE showed the same pattern of incubation time, clinical signs and brain lesions as mice inoculated with tissues from patients with vCJD. This provides evidence that BSE and vCJD have the same signature or are the same "strain". In addition, sporadic CJD and known scrapie strains were not similar to vCJD or BSE.

Results from a study published by Dr. John Collinge and colleagues of Imperial College School of Medicine, London, UK strongly support Bruce's results. Collinge's paper reports findings of BSE transmission to transgenic mice expressing only human PrP.

Another paper by Collinge et al. in the October 24, 1996 edition of *Nature* also provides data to support the association between vCJD and BSE.

More recently, studies using transgenic animals expressing the bovine PrP have supported the view that BSE infected cattle are responsible for vCJD. These mice not only propagated the BSE infectious agent in the absence of a species barrier, but also were highly susceptible to vCJD. Furthermore, the transgenic mice inoculated with either vCJD or BSE had indistinguishable disease characteristics.

Where has vCJD been Detected?

The variant form of CJD has been detected in the United Kingdom. The UK CJD Surveillance Unit provides a monthly update. There have also been 6 cases of vCJD in France, 1 in Ireland, and 1 probable case in the United States and Italy.

On April 18th, 2002, the Florida Department of Health and the CDC reported a likely case of new variant Creutzfeldt Jakob disease (vCJD) in a 22-year-old citizen of the United Kingdom living in Florida. The clinical diagnosis was recently made at a hospital in the U.K. and she has since returned to the U.S. Information provided by the U.K. indicates that the patient's clinical condition and history are consistent with vCJD acquired in the U.K. However, the only way to confirm a diagnosis of vCJD is through study of brain tissue obtained by a brain biopsy or at autopsy.

New variant CJD is a rare, degenerative, fatal brain disorder that emerged in the U.K. in the mid-1990s. Although experience with this new disease is limited, evidence to date indicates that there has never been a case transmitted from person to person. Rather, the disease is thought to result from consumption of cattle products contaminated with an agent that causes a disease called bovine spongiform encephalopathy (BSE, commonly known as mad cow disease). To date, no case of this cattle disease has been identified in the United States by the USDA.

If confirmed, this would be the first case of vCJD reported in a U.S. resident. However, because the disease is thought to have a long incubation period, CDC believes the patient acquired the disease while living in the U.K.

For more information, please visit the CDC web site or the Florida Department of Health Web site.

Transmission of BSE

There is no evidence that BSE spreads horizontally, i.e., by contact between unrelated adult cattle or from cattle to other species. Some evidence suggests that maternal transmission may occur at an extremely low level. Results of British research show that there is approximately a 9-percent increase in the occurrence of BSE in offspring of BSE-affected dams as compared to calves born to dams where BSE was not detected. The study did not ascertain if this was the result of genetic factors or true transmission. The research did however point out that at this level if maternal transmission does occur it alone will not sustain the epidemic (Wilesmith et al. 1997).

A recently published study found no evidence of disease transmission via embryos collected from cows with BSE. The embryos were collected and handled in accordance with international health standards (Wrethall et al., 2001).

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	28-04	5/20/04

FSIS SAMPLE COLLECTION FROM CATTLE CONDEMNED DURING ANTE-MORTEM INSPECTION FOR THE BOVINE SPONGIFORM ENCEPHALOPHATHY (BSE) SURVEILLANCE PROGRAM

NOTE: FSIS PERSONNEL ARE NOT TO IMPLEMENT THE SAMPLE COLLECTION PROCEDURES IN THIS NOTICE UNTIL JUNE 1, 2004

I. PURPOSE

This notice contains updated information from FSIS Notice 18-03, dated 5/27/03. That notice expires on 6/1/04. In light of recent events, FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing. Therefore, FSIS is issuing new sample collection, documentation, and shipping procedures to inspection program personnel, particularly Public Health Veterinarians (PHVs). Specifically trained FSIS PHVs will collect the brain samples. The samples will be shipped to the USDA Animal and Plant Health Inspection Service (APHIS) National Veterinary Services Laboratory (NVSL) in Ames, Iowa, or another APHIS-designated laboratory.

II. BACKGROUND

BSE is a reportable disease in the United States. In cooperation with FSIS, APHIS leads an ongoing, comprehensive, interagency surveillance program for BSE. Using the Federal Meat Inspection Act, 21 U.S.C. 603, part of the FSIS ante-mortem examination and inspection procedure will include the collection of a brain sample from cattle. For the first time, FSIS PHVs will collect brain samples from cattle that are condemned during ante-mortem inspection at federally-inspected establishments. The APHIS Area Veterinary Inspector-in-Charge (AVIC) will focus upon sample collection activities by APHIS at locations other than federally-inspected establishments (e.g., rendering operations and on-farm). FSIS PHVs will take samples from all cattle showing signs of

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; TRA; ABB; TSC; Import Offices	**NOTICE EXPIRES:** 6-01-05	**OPI:** OPPED

central nervous system (CNS) disorders, as well as the types of cattle that may be at higher risk for being infected with the agent believed to cause BSE, based, in part, on European data. These cattle, while at federally-inspected establishments, are under the control of FSIS and will have the brain sample collected either by the trained FSIS

PHV or an available APHIS technician with direct supervision and oversight by the FSIS PHV.

Under FSIS Notice 18-03 FSIS contacted APHIS whenever specific cattle were presented for ante-mortem inspection (e.g., cattle exhibiting CNS symptoms). The notice also stated that an APHIS veterinarian will be responsible for collecting the brain sample. When FSIS Notice 18-03 expires on June 1, 2004, APHIS will no longer collect the brain samples.

As instructed in this notice, FSIS personnel will collect brain samples from ante-mortem condemned cattle, and especially from any cattle exhibiting CNS symptoms, and will submit the samples to APHIS for analysis. APHIS will no longer collect brain samples at FSIS-inspected establishments.

III. Should the FSIS PHV have an awareness meeting with the establishment regarding the BSE testing process?

A. Yes, before June 1, 2004, the FSIS PHV needs to meet with the establishment to explain the procedure for the collection of brain samples for BSE testing. At this meeting, the FSIS PHV and management should discuss:

1. the FSIS procedures set forth in this notice.

2. how the establishment will ensure that ante-mortem condemned cattle will be segregated from other cattle,

3. whether the establishment will remove the head under the direct supervision of the FSIS PHV, or whether the FSIS PHV will have to remove the head,

4. whether the establishment has existing arrangements with APHIS under which the establishment delivers the carcass to deadstock facilities, renderers, or other animal disposition facilities so that APHIS can collect brain samples. If so, the FSIS PHV is to notify his or her District Office (DO).

5. how the establishment will hold the ante-mortem condemned animal (head and carcass) until removal from the premise,

6. how the establishment will dispose of the condemned carcass (i.e., picked up by renderer, sent to a landfill) and that the establishment is to maintain records, as required in 9 CFR 320.1, regarding the disposition of the condemned carcasses, and

7. that the establishment may obtain additional information about the sampling program from http://www.aphis.usda.gov/lpa/issues/bse/bse.html.

B. In a memorandum of interview, the FSIS PHV is to document who was present at the awareness meeting, the date and time of the meeting, what was discussed and decided regarding the issues above, and any documents that were shared with management.

C. The FSIS PHV is to maintain a copy of the memorandum of interview in the official government file, provide a copy to the plant management, and electronically mail a copy to the APHIS AVIC.

IV. Who, in FSIS, will collect the brain tissue sample?

Trained FSIS PHVs will collect the sample from ante-mortem condemned cattle. FSIS, along with APHIS, will sponsor a special sample collection training session prior to June 1, 2004. Most establishments with a history of having ante-mortem condemned cattle will soon have a trained FSIS PHV on-site. Other establishments, such as those in remote locations, may have a trained FSIS PHV come to the establishment to collect samples. Still, other establishments may have an APHIS technician on-site to collect samples. However, the APHIS technician will, for purposes of brain sample collection, collect the sample with direct supervision by the FSIS PHV.

V. What cattle will be sampled by FSIS for BSE surveillance purposes?

A. All ante-mortem condemned cattle at federally-inspected establishments will have a portion of the brain collected by the specially trained FSIS PHV, except for 1) cattle that are 400 pounds or less (which may be referred to as “veal calves”) with characteristics of immature cattle, condemned by the FSIS PHV but that do not exhibit CNS signs, and 2) cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b).

B. The FSIS PHV or the APHIS technician under the supervisory authority of the FSIS PHV will collect the brain sample from cattle condemned by the FSIS PHV during ante-mortem inspection at the federally-inspected establishment. Cattle off-loaded from the transport vehicle onto the premises of the federally-inspected establishment, whether dead or alive, will be sampled by the FSIS PHV for BSE after the cattle have been condemned during ante-mortem inspection. In addition, cattle passing ante-mortem inspection but later found dead prior to slaughter will be condemned and be sampled by the FSIS PHV. The FSIS PHV is to make all final disposition decisions regarding whether cattle should be condemned in accordance with 9 CFR part 309.

VI. What information will the FSIS PHV maintain regarding the identity of condemned cattle?

The FSIS PHV will ensure the collection and documentation of all animal

identification associated with cattle condemned during ante-mortem inspection that are to be sampled by FSIS. The FSIS PHV is to attach the "U. S. Condemned" tag cattle condemned during ante-mortem inspection in accordance with 9 CFR 309.13. The FSIS PHV is to also ensure that available records associated with the documentation of the ownership of the cattle are maintained along with a file on each BSE-sampled animal. This documentation will facilitate trace back in the event that the sample result is positive for BSE. The documentation should include records in accordance with 9 CFR 320.1. **NOTE**: The slaughter establishment should not be considered the owner of the animal as a default. Once the brain sample has been collected from the head and all animal identification has been recorded and removed, the head and remainder of the animal are to be disposed of in accordance with 9 CFR 314. The establishment is to ensure that unsanitary conditions do not result from inappropriate holding of the head and carcass while the condemned material is awaiting pick-up by a renderer or by other means of transport or disposal.

VII. What is the process for ensuring that the condemned cattle (e.g., the carcass and head minus the brain sample) are removed from the establishment?

The FSIS PHV should ensure that unsanitary conditions are not created by the presence of the condemned cattle (9 CFR part 416). The establishment is responsible for the disposal of the condemned cattle in accordance with 9 CFR part 314. In cases in which the establishment cannot obtain transport services for removal of the condemned cattle in a timely manner, the establishment should contact the APHIS AVIC. Also, the establishment is to maintain records regarding the disposition of the condemned cattle in accordance with 9 CFR 320.1.

VIII. How will the cattle be handled in order for the FSIS PHV to collect the brain tissue sample?

A. If condemned cattle are alive, the establishment is required to humanely euthanize the cattle, in accordance with 9 CFR 309.13. The head should be removed as quickly as possible in order to collect the brain sample. If the establishment does not make arrangements to remove the head, the FSIS PHV should notify the Front-line Supervisor that the brain sample collection will need to be taken as a priority over other ante-mortem or post-mortem procedures.

B. The brain sample should be collected either in the inedible area of the establishment or other area set aside for such collection in which edible product cannot become adulterated due to the creation of an unsanitary condition. The establishment, APHIS technician, and FSIS personnel are to take proper sanitary measures before returning to edible areas of the establishment after brain sample collection, in accordance with 9 CFR 416.5.

IX. Will the FSIS PHV receive special sample boxes and instructions for shipping the sample?

A. Establishments with a history of high ante-mortem condemnation rates for slaughter will be identified by FSIS and the FSIS PHV at these establishments will receive multiple special sample boxes and shipping instructions from APHIS. Establishments without a history of high ante-mortem condemnation rates for slaughter will be identified by FSIS and the FSIS PHV at these establishments ultimately will receive sample boxes and shipping instructions from APHIS. The brain samples will be shipped to the APHIS NVSL or other designated laboratory, but not to an FSIS laboratory. (See Attachment 1).

B. After June 1, 2004, if cattle are condemned at ante-mortem inspection and the trained FSIS PHV does not have a special sample box and shipping instructions, the brain sample is to be collected by the FSIS PHV and put into a plastic bag and securely stored in a cooler (not a freezer). The sample is not to pass through or to be stored in areas of the establishment where edible product is produced. This may mean that the sample has to be stored under refrigeration outside of the official establishment. If there is no trained FSIS PHV or APHIS technician immediately available to collect the brain sample, the FSIS PHV should have the establishment save the head, brain intact, and place the head in a cooler (not a freezer) to reduce post-mortem autolysis of the brain. The head should be placed into a plastic bag and securely stored as explained above.

X. What is included in the special sample box and shipping instructions?

The special sample box from APHIS will include a sample collection kit (e.g., equipment to obtain the brain sample, a tube for placing the packaged sample within the shipping container, and identifying labels to affix to the sample). The FSIS PHV is to enter the "U.S. Condemned" tag number onto the APHIS-supplied forms. FSIS should record any APHIS identifying bar code labels onto the FSIS condemnation certificate. The shipping container will be picked up by FedEx, using the APHIS contract for overnight shipping. If there is a problem with the FedEx pickup of BSE samples, the FSIS PHV should contact the DO. The DO will contact the APHIS contact person responsible for the APHIS FedEx contract. **NOTE**: In situations where the last FedEx pick-up for the day has been missed or the sample is collected on a day when FedEx does not pick up, store the samples as discussed in paragraph IX. B. until the next available FedEx pick up day.

XI. What information will the FSIS PHV identify on the condemnation report and the APHIS sample request form?

The FSIS PHV will continue to complete the condemnation form, FSIS Form 6000-13, (Certification of Ante-mortem or Post-mortem Disposition of Tagged Animals) and FSIS Form 6150-1 (Identification Tag – Ante-mortem). The FSIS PHV should pay special attention when providing a full description of the reason for the condemnation on FSIS Form 6000-13 and fully fill out FSIS Form 6150-1 (i.e., identification, breed, sex,

reason for tag, and clinical signs). In addition, the FSIS PHV is to include similar information on the APHIS sample request form, including the estimated age of the cattle (see http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/ofo/tsc/index.htm.)
The FSIS PHV should give special consideration to any age documentation that accompanies cattle to the federally-inspected establishment, in lieu of a dentition determination.

XII. How will sample results be reported?

APHIS NVSL will report the sample result to the establishment. FSIS is working with APHIS on a process to also include the FSIS PHV in the reporting of the sample result.

XIII. Will the FSIS PHV collect samples from healthy-appearing cattle that are not condemned?

The details regarding the testing of healthy appearing cattle 30 months of age and older by FSIS or APHIS is still under discussion. This group of cattle is much less likely to demonstrate BSE infectivity than those that show CNS symptoms or that have died on-farm or otherwise, or that are ante-mortem condemned. Thus, the details for the portion of the BSE surveillance program involving healthy-appearing cattle will issue in a separate FSIS notice at a later date.

XIV. What form will the FSIS PHV complete to record each sample taken?

The FSIS PHV will complete FSIS Form 5000-9, BSE Sampling Tracking Sheet located in *MS Outlook, Public Folders, All Public Folders, Agency Issuances, Forms, FSIS 5000 series* to report every sample collected. To facilitate APHIS reimbursement for the sample, the FSIS PHV will send a hard copy of the Form to the Financial Processing Center, Financial Management Division.

Refer questions to the Technical Assistance and Correlation Division, Technical Service Center at (402) 221-7400.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy, Program, and Employee Development

Attachment 1

Designated Laboratories for BSE Sample Submission

State where sample was collected	Designated laboratory
Arizona, California, Nevada	California Animal Health and Food Safety Lab System University of California – Davis, CA
Colorado, Kansas, Missouri, Nebraska, North Dakota, South Dakota, Utah, Wyoming	Colorado State University Veterinary Diagnostic Lab Ft. Collins, CO
Arkansas, Louisiana, New Mexico, Texas	Texas Veterinary Medical Diagnostic Laboratory College Station, TX
Minnesota (or NVSL), Wisconsin	Wisconsin Animal Health Laboratory Madison, WI
Idaho, Montana, Oregon, Washington	Washington State University Animal Disease Diagnostic Lab Pullman, WA
Alabama, Florida , Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Virginia	Athens Diagnostic Laboratory, College of Veterinary Medicine University of Georgia; Athens, GA
Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania (all Pennsylvania), Rhode Island, Vermont	NY State College of Veterinary Medicine Veterinary Diagnostic Laboratory, Cornell University Ithaca, NY
Alaska, Hawaii, Illinois, Indiana, Iowa, Kentucky, Minnesota (or WI), Ohio, Puerto Rico, West Virginia	USDA, APHIS, National Veterinary Services Laboratory (NVSL) Ames, IA

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	29-04	5-27-04

QUESTIONS AND ANSWERS FOR FSIS NOTICE 28-04 REGARDING ANTE-MORTEM CONDEMNED CATTLE

I. PURPOSE

This notice provides clarification to FSIS Notice 28-04, FSIS Sample Collection From Cattle Condemned During Ante-Mortem Inspection for the Bovine Spongiform Encepholophathy (BSE) Surveillance Program. The following issues are addressed:

1. Expectations regarding the Animal and Plant Health Inspection (APHIS) arrangements, through the APHIS Area Veterinarian-in-Charge (AVIC), with establishments for APHIS to test condemned cattle at a central location,

2. Additional questions FSIS Public Health Veterinarian (PHV) should seek answers to either at the awareness meeting or at the on-going weekly meetings,

3. Why FSIS Notice 28-04 stated FSIS would not collect brain samples from cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b),

4. A corrected form number for reimbursement associated with FSIS sample collections, and

5. Miscellaneous questions.

Also, this notice issues a revised list of the laboratories where PHVs are to send samples.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; TRA; ABB; TSC; Import Offices	**NOTICE EXPIRES:** 6-1-05	**OPI:** OPPED

II. QUESTION AND ANWSERS FOR EACH ISSUE

A. *Issue 1. Expectations regarding the APHIS arrangements with establishments to test condemned cattle at a central location*

Question: What controls does FSIS expect the establishment to have in place in order for FSIS to recognize an APHIS arrangement to have FSIS condemned cattle transported off-site from the establishment to an APHIS central sample collection point?

Response: FSIS will recognize such arrangements if establishments provide procedures for ensuring that the PHV will be notified that the condemned cattle are delivered to the APHIS central sample collection point for brain sample collection. The notification by the establishment provides information that is required under the recordkeeping requirements in 9 CFR 320.1. **NOTE**: Condemned cattle will continue to be denatured in the presence of an inspector at the establishment, and the U.S. Condemnation tag will be removed by the FSIS PHV. The FSIS PHV will not be able to close out the files on these condemned cattle, however, until notified by the establishment that these condemned cattle were delivered to the APHIS central sample collection point.

In order for the FSIS PHV to recognize the arrangement answers to the following issues should be provided:

1. The process for denaturing the cattle in a manner that would not affect the collection of a brain sample,

2. How the FSIS condemnation tag numbers (the tag are removed only by FSIS) will remain associated with the condemned cattle (this does not mean physically attached),

3. Who will remove the cattle from the establishment and transport it to the APHIS central sample collection point. (The transporter of the condemned cattle is to be registered with FSIS in accordance with 320.5),

4. The location of the APHIS central sample collection point, including the address and a contact at the location,

5. How the APHIS sample collection representative is made aware that FSIS condemned cattle are being delivered to the APHIS central sample collection point, and

6. How the establishment will provide notification to the FSIS PHV that the condemned cattle were delivered to the APHIS central sample collection point.

Question 2: What will happen if an establishment that chooses to send condemned cattle to an APHIS central sample collection point fails to have or maintain appropriate procedures and documentation that demonstrates that the cattle were delivered and arrived at the APHIS central collection point?

Response: The failure of the establishment to ensure that condemned and denatured cattle are appropriately controlled, tracked, and delivered to the central collection point will result in the Agency no longer allowing condemned cattle to be removed from the premises for sampling and may be treated as a prohibited act, in violation of the Federal Meat Inspection Act, 21 U.S.C. 610, and the regulations that FSIS has adopted under 21 U.S.C. 603(a) and 9 CFR 314.9.

B. *Issue 2. Questions that the (PHV) should ask the establishment management at the awareness meeting or at the on-going weekly meeting.*

Answers to the following questions are necessary to better understand the establishment's identification and control procedures for dead cattle, non-ambulatory disabled cattle, and condemned ambulatory cattle:

For dead cattle

1. Does the establishment have arrangements with APHIS for off-site sample collection? (If yes see II. A. of this notice).

2. Will dead cattle be off-loaded at the official premises, or will they be transported to an APHIS central sample collection point?

3. If dead cattle are off-loaded in an establishment's holding pens, how will the cattle be segregated to provide for sample collection?

4. Has an appropriate area been designated for collecting the brain sample from condemned dead cattle?

5. Who will be removing the head of condemned cattle?

6. Has a procedure been established for containing the condemned cattle (and parts, including blood) during sample collection in order to prevent an insanitary condition?

7. Has a procedure been established to properly clean and sanitize the sampling area? [**NOTE**: Special cleaning and sanitization of pens and holding areas is not required; normal cleaning is sufficient.]

8. Will the sampled cattle (carcass and head) be held pending receipt of laboratory results, or, alternatively, how will the sampled cattle be disposed of? [**NOTE**: There is no requirement by FSIS to hold the sampled cattle after the brain sample has been collected. However, the establishment should contact the APHIS AVIC if there is a problem with the timely pick-up or removal of sampled cattle.]

For non-ambulatory disabled (live) cattle

1. Where will cattle be euthanized (e.g., in the establishment's holding pens or on the transport vehicle)? [**NOTE**: Condemned cattle must be euthanized at the establishment, under the supervision of FSIS, in order to ensure that the cattle are humanely handled. Condemned cattle cannot be removed from the establishment and euthanized at an APHIS central sample collection point. The establishment should ensure that the method of euthanization does not impact the quality of the brain sample (e.g., special low velocity 22 ammunition into the forehead of the condemned cattle would kill the animal, but would NOT damage the part of the brain for BSE sampling; a bigger shot would have the capacity to destroy more of the brain, possibly the brainstem, and would impact the quality of the brain sample).]

2. Are all provisions for handling dead cattle being followed?

For condemned ambulatory (live) cattle

Are all provisions for handling non-ambulatory disabled (live) cattle being followed?

C. *Issue 3. Why FSIS Notice 28-04 stated that FSIS would not collect brain samples from cattle condemned on ante-mortem inspection that the establishment elects to have treated pursuant to 9 CFR 309.13(b).*

Question: In the May 20, 2004 memorandum from the APHIS and FSIS Administrators regarding the BSE sampling of condemned cattle, there was no mention of an exemption from sampling for cattle being treated pursuant to 9 CFR 309.13(b). However, FSIS Notice 28-04, also dated May 20, 2004, does include the exemption (see Section V. A.). Which policy statement is applicable to FSIS?

Response: FSIS Notice 28-04 contains the procedures that FSIS inspection program personnel should follow. Although the memorandum from the Administrators did not specifically address this exemption, the exemption was already provided for in FSIS regulations and was not deemed necessary to include in the memorandum. A copy of the memorandum is attached.

D. *Issue 4. Corrected form number for reimbursement associated with FSIS sample collections.*

Question: What is the correct form number to be completed by FSIS in order to ensure that FSIS gets reimbursed by APHIS for brain sample collection?

Response: The corrected form number is FSIS Form 5000-11 (BSE Sampling Tracking Sheet). FSIS Notice 28-04 incorrectly listed the form number as FSIS Form 5000-9.

E. *Issue 5. Miscellaneous questions.*

Question 1: Do cattle have to be presented for ante-mortem inspection in order

to be subject to sample collection?

Response: All cattle that are off-loaded from transportation vehicles are considered to be presented for inspection and, therefore, are to be test under FSIS Notice 28-04, where applicable. Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

Question 2: Is the PHV responsible for determining whether the sample is of acceptable quality, (i.e., whether autolysis has not occurred), before submitting a sample to the laboratory?

Response: The PHV is not responsible for making these determinations. All samples are to be taken and submitted to the laboratory.

Question 3: Can PHVs get rabies vaccinations?

Response: Yes, however rabies vaccinations are volunatry. Only PHVs who are actually involved with BSE sample collection will be eligible for reimbursement on the vaccination series. PHVs should make arrangements for the vaccinations with their private physician. PHVs should contact their Front-line supervisor for approval on reimbursement prior to beginning the three shot vaccination series.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy, Program, and Employee Development

{See Page 21 of Procedure Manual for Bovine Spongiform Encephalopathy (BSE) Surveillance for updated listing of designated laboratories.}

Attachment

Designated Laboratories for BSE Sample Submission

State where sample was collected	Designated laboratory
Arizona, California, Nevada	CAHFS-Thurman Bldg. West Health Science Drive UC Davis Davis, CA 95616
Colorado, Kansas, Missouri, Nebraska, North Dakota, South Dakota, Utah, Wyoming	Dr. Barbara Powers CO State University Vet Diagnostic Laboratory Ft. Collins CO 80523
Arkansas, Louisiana, New Mexico, Texas	Texas A & M TVMDL Pathology Department 1 Sippel Road College Station, TX 77843
Minnesota (or NVSL), Wisconsin	Dr. Phil Bochsler WVDL - TSE Laboratory 6101 Mineral Point Rd. Madison, WI 53705
Idaho, Montana, Oregon, Washington	Washington State University WADDL Animal Disease Diagnostic Laboratory Bazzler Bustad Hall Room 155-N Pullman WA 99164-7034
Alabama, Florida , Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Virginia	Athens Diagnostic Laboratory College of Vet Med Doris Miller University of Georgia Athens, GA 30602
Connecticut, Delaware, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania (all Pennsylvania), Rhode Island, Vermont	Cornell University Animal Health Diagnostic Laboratory Department of Biomedical Sciences S2-124 Schurman Hall Ithaca, NY 14853
Alaska, Hawaii, Illinois, Indiana, Iowa, Kentucky, Minnesota (or WI), Ohio, Puerto Rico, West Virginia	USDA, APHIS, National Veterinary Services Laboratory (NVSL) Ames, IA

USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

J.L. Whitten Bldg. 312E
1400 Independence Ave.
Washington, D.C. 20250

MEMORANDUM FROM THE ADMINISTRATORS

FROM: W. Ron DeHaven
Administrator
APHIS
MAY 20 2004

Barbara Masters
Acting Administrator
FSIS
MAY 20 2004

TO: VSMT
Regional Directors/AVICs
Veterinary Services
District Managers
Field Operations

SUBJECT: Policy statement regarding BSE sampling of condemned cattle at slaughter plants – for immediate implementation.

This notice serves as follow-up guidance to the joint memo of May 5, regarding BSE surveillance sampling at slaughter plants. These enhanced procedures will be effective June 1, 2004:

FSIS will collect samples for BSE testing from cattle at federal establishments as described below:

- All cattle – regardless of age, including veal calves - condemned by FSIS upon antemortem inspection for CNS impairment will be sampled for BSE by FSIS personnel. Of the cattle condemned every year, approximately 300 are condemned for signs of CNS impairment.
- All cattle – with the exception of veal calves – condemned by FSIS upon antemortem inspection for any reason other than CNS will be sampled for BSE by FSIS personnel.
- APHIS will coordinate with the FSIS State Liaison Director to assist in assuring sample collection from State-inspected facilities.
- FSIS (or the state inspector where applicable) will collect brain tissue samples from dead cattle that arrive and are offloaded on the premises of FSIS-inspected establishments.

Furthermore:

- APHIS will obtain samples from animals that are dead on arrival –but not offloaded -- through their routine sampling and agreements with deadstock facilities, renderers, and other animal disposal facilities.

APHIS *Safeguarding American Agriculture*
APHIS is an agency of USDA's Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer

MEMORANDUM FROM THE ADMINISTRATORS
Page 2

- In cases where APHIS has funded a technician to remain on the premises and take samples at FSIS-inspected establishments, that technician is under the oversight of the FSIS inspector-in-charge.
- FSIS and APHIS will work with plant management to ensure appropriate arrangements for removal or disposal of carcasses from sampled animals.
- FSIS and APHIS will consider alternative arrangements to test all cattle described above. Such arrangements may make use of previously established arrangements with deadstock facilities, renderers and other animal disposal facilities. These arrangements must include verification and documentation that cattle are sampled.
- USDA will establish a toll-free number for USDA employees and farmers/industry to call if they have any question or concern about BSE sampling. Calls will be routed to the appropriate APHIS Area Veterinarian in Charge for appropriate and timely follow-through, and AVIC's will be responsible for immediately elevating any issues that may potentially indicate a broader systemic problem. AVICs are also responsible for alerting the appropriate FSIS District Manager regarding any issues of joint concern.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	33-04	6-14-04

COMPLIANCE AND INVESTIGATIONS DIVISION (CID) PROTOCOL FOR OFF-SITE COLLECTION OF BRAIN SAMPLES FOR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) TESTING

I. PURPOSE

This notice issues the protocol for CID inquiries related to the sample collection of brain samples for BSE testing of bovine animals that were "U.S. Condemned" on ante-mortem inspection at federally-inspected establishments and moved from the federally-inspected establishment to an off-site sample collection location (See FSIS 28-04 and 29-04). The sample collection locations are typically rendering operations, 3D/4D operations, landfills, collection sites, pet food manufacturers, and other non-federally inspected establishments or locations. The Animal and Plant Health Inspection (APHIS) Area Veterinarian-in-Charge (AVIC), APHIS technician or APHIS contractor will collect the brain sample. The purpose of the protocol is to verify that ante-mortem condemned cattle arrive at the locations and the Animal and Plant Health Inspection Service (APHIS) is aware of the cattle's arrival.

II. VERIFICATION OF REGISTRATION

Program Investigators (PIs) are to inquire if the subject firm has completed FSIS Form 5020-1, Registration of Meat and Poultry Program Handlers, in compliance with 9 CFR 320.5, and as further described in FSIS Notice 27-04 dated May 17, 2004. If the subject firm is not registered, the PI should give a copy of the form to management. The name of the management official that was presented the form and the date are to be recorded in the PI Daily Activity Report (DAR).

III. NOTIFICATION

The appropriate CID Regional Manager (RM) will be notified by the District Office of establishments that have an agreement with APHIS for the off-site sample collection of brains. The CID RM will notify the appropriate District Manager if condemned carcass does not arrive at the off-site sampling location.

IV. PROCEDURES FOR RECORDING OFF-SITE SAMPLE COLLECTION

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; TRA; ABB; TSC; Import Offices	**NOTICE EXPIRES:** 7-01-05	**OPI:** OPPED

LOCATIONS INTO THE PLANNED COMPLIANCE PROGRAM (PCP)

PIs are to record all off-site sample collection locations they visit as status code "B" in the Planned Compliance Program (PCP). They are to assign the sample collection location a primary business code "14" if no other type of business is conducted at the location. If the location conducts any other type of business, the PIs are to assign the appropriate business code as found under Appendix B in the Compliance Officer Manual and assign business code "14" as the secondary code. PIs are to complete the remaining inquiry and PCP documentation in the following manner:

A. Meeting with APHIS AVIC, Technician, or Contractor:

1. Conduct an entrance conference with the APHIS AVIC, technician, or contractor assigned to collect brain samples from FSIS ante-mortem condemned animals received from federally inspected establishment. Identify yourself, explain the purpose of your visit, and answer questions as they relate to the sampling initiative,

2. Review and discuss the procedures conducted when condemned cattle are delivered, and how APHIS is notified that the condemned cattle have arrived.

Seek answers to such questions as:

a. How does the firm prepare the condemned cattle for sampling?

b. How many hours per day and days per week are the sample collectors at the location, and are there times when a carcass would have to be held at the location because there was no sample collector available?

3. Discuss sampling procedures conducted by the APHIS AVIC, technician, or contractor.

B. Meeting with Off-Site Sample Collection Point Plant Management:

1. Conduct an entrance conference with management and identify yourself. Explain the purpose of your visit and answer questions.

2. Discuss the certification that the firm has from APHIS for receiving ante-mortem condemned cattle from federally inspected establishments and collecting samples.

3. Discuss the agreement that the firm has with the federally inspected establishments for receiving FSIS ante-mortem condemned cattle and collecting samples.

4. Discuss procedures that the firm conducts when receiving condemned cattle, preparing cattle for sampling, disposition of cattle after being sampled.

5. Document the registration status of the firm.

C. Facility Observations:

1. Observe and record the area set aside for collection of brain samples and carcass disposition area.

2. Conduct a physical observation of cooler for storing brain samples *(if available).*

D. Examine or Observe Handling of Condemned Cattle, Storage, and Shipping Practices:

1. Observe U.S. condemned cattle received from federally inspected establishments that will be sampled for BSE.

2. Observe the proper disposal of the condemned carcass and parts after it has been sampled.

E. Records Review:

Review all records for completeness and accuracy (i.e., receiving records, ownership and trace-back records, laboratory forms, fed-ex air bills, sample results, APHIS records, etc.). During initial reviews, it will be important to capture all salient documentation in the PCP for future use.

F. Exit Meeting with the APHIS AVIC, Technician, or Contractor and Off-Site Sample Collection Point Management:

1. Conduct exit conferences with the APHIS AVIC, technician, or contractor and the off-site sample collection point management. The PI should decide whether to do this jointly or independently based on his or her observations and sound reason.

2. Ask questions to clarify observations.

3. Discuss findings.

4. Provide the APHIS technician or contractor and collection point management the opportunity to ask questions.

5. Advise them that a PI may conduct follow-up visits.

If the PIs have concerns about the sample collection activities he or she is to note this in the PCP and contact the RM if necessary.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy, Program, and Employee Development

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE	40-04	7/29/04

ADDITIONAL BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) SURVEILLANCE SAMPLING QUESTIONS AND ANSWERS

The Food Safety and Inspection Service (FSIS) is issuing this notice to provide answers to questions FSIS personnel have asked regarding FSIS' BSE surveillance sampling program.

I. Electronic Animal Disposition Reporting System (eADRS) and Performance- Based Inspection System (PBIS)

A. Question: What does an FSIS Public Health Veterinarian (PHV) document in eADRS when *non-ambulatory disabled* cattle are euthanized at the election of the establishment? Examples would be when the plants humanely euthanize an animal prior to the arrival of a PHV, or when an animal becomes non-ambulatory after antemortem inspection has been conducted?

Answer: In such cases, the antemortem disposition would be "dead," and the PHV records this in eADRS under "deads." The category "non-ambulatory (plant condemned)" is no longer available for cattle in eADRS. Also, in such cases, the PHV may write "Dead (Plant rejected and euthanized)" in the "Diagnosis/Condition" column of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals.

B. Question: Does the PBIS system schedule the brain sample collection for BSE testing?

Answer: No. FSIS personnel collect samples in accordance with FSIS Notices 28-04 and 29-04.

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; TRA; ABB; TSC; Import Offices	**NOTICE EXPIRES:** 8/01/05	**OPI:** OPPED

II. Alternative Sampling -- Animal and Plant Health Inspection Service (APHIS) Central Sample Collection Point

A. Question: What are the animal identification collection and documentation procedures for cattle sampled under an accepted "alternative program" (APHIS central sample collection point)?

Answer: Normal documentation procedures apply, including recording the condemned tag number and all animal identification (e.g., eartag, backtag) on FSIS Form 6150-1 (Identification Tag-Antemortem). However, in this case the animal identification tags or devices will remain on the animal or handled in accordance with an accepted alternative method. Condemned tags should be removed prior to transport and after the carcass has been denatured in accordance with 9 CFR 314.

B. Question: What responsibility does the FSIS PHV have to provide information to plant management for cattle sampled under an acceptable alternative program (APHIS central sample collection point)?

Answer: The FSIS PHV's responsibility is to supply plant management with copies of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals, that includes the condemned tag number. The establishment may also request to make copies of FSIS Form 6150-1. The establishment may use this information to fulfill the expectation of FSIS Notice 29-04 concerning alternative programs to ensure that the animal identification information and condemned tag number (although not physically attached) remain associated with the animal.

III. State, Talmadge-Aiken (T/A), and Custom-Exempt Establishments

A. Question: How is the sampling handled at T/A plants?

Answer: FSIS will perform sampling in TA plants. If sample collection is needed, the state coordinator should contact the District Office (DO).

B. Question: How is the sampling handled at State plants?

Answer: State plants should contact the State Area Veterinarian-in-Charge (AVIC) for sample collection. Any alternative programs for sampling off-premises must be consistent with FSIS Notice 29-04.

C. Question: At federally-inspected establishments, who is responsible for collecting brain samples from animals designated "for custom slaughter" and that are non-ambulatory disabled cattle or cattle that exhibit Central Nervous System (CNS) signs?

Answer: When an establishment's schedule of operations indicates that the establishment is operating under custom exempt, those animals are exempt from the inspection requirements of the Federal Meat Inspection Act (FMIA). Because custom exempt cattle that are non-ambulatory disabled or that exhibit CNS signs are unfit for food, inspection program personnel who observe cattle with these signs being

slaughtered for food are to detain the carcass and head in accordance with FSIS Directive 8410.1, rev 2. Inspection program personnel also are to contact the DO.

The DO will assign a PHV to collect and submit a brain sample for BSE testing. In addition, the PHV is to notify the OPEER Regional Manager through supervisory channels.

IV. Sample Collection

A. Question: How will personnel be dispatched to collect samples at federally-inspected establishments?

Answer. District Managers will handle this within their districts according to staffing needs.

B. Question: Does the PHV have to be present when the head is removed?

Answer: While it is preferable that the PHV be present at the time of head removal, some situations (e.g., non-ambulatory disabled cattle that have been euthanized by the plant) may require removal of the head prior to the arrival of a PHV. The process for removal, storage, and control of the head and carcass denaturing should be decided during the awareness meeting with plant personnel if it is anticipated that removal of the head in the absence of the PHV may be necessary. The establishment's process should also ensure that sufficient controls are in place to maintain the identity of the animal.

C. Question: Are instruments used only to harvest the sample required to be sanitized?

Answer: No, but thorough washing is recommended. It would be preferable that dedicated or disposable instruments be used to harvest samples for BSE testing.

D. Question: How is the determination made that the animal is 400 lb. or less?

Answer: The PHV must rely on his or her judgment, expertise, or any other resources (e.g., records or actual weighing of animal) to determine the approximate weight of the animal.

E. Question: Are dead calves (i.e., less than 400 lbs.) sampled?

Answer: No, because such animals are not part of the high-risk population identified by APHIS.

F. Question: Who is responsible for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises"?

Answer: Such cattle would be subject to sampling by APHIS.

G. Question: What is considered to be "presented for antemortem inspection"?

Answer: Live cattle that are off-loaded from transportation vehicles are considered to be presented for inspection and, therefore, are to be tested under FSIS Notice 28-04, where applicable. Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be promptly re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

H. Question: Does the head always have to be removed when harvesting samples?

Answer: PHVs have been trained to remove the head in order to collect the sample. If a plant is exposing the brain stem for sample collection by the PHV, the PHV will determine whether a sample can be adequately collected. Although PHVs can work with the plant to determine other efficient and suitable methods, decisions on the adequacy of sample collection procedures are the responsibility of the PHV.

I. Question: How is BSE sampling handled at small plants where there is no PHV?

Answer: The PHV responsible for final disposition in that plant should be contacted. If the animal is condemned, the DO will follow its procedures for arranging for sample collection by a trained PHV.

J. Question: What procedures should be followed for head removal after an animal is U. S. condemned and euthanized?

Answer: It is recommended that the establishment remove the head for FSIS sampling as soon as possible. FSIS sampling (including head removal if not performed by the establishment) may take precedence over other antemortem or postmortem procedures.

K. Question: Can the plant use the suspect pen for sampling?

Answer: The plant can use the suspect pen, provided humane handling and inspection of other animals in the suspect pen is not affected. Regardless of where the sampling is performed, sanitary conditions must be maintained.

V. Carcass Disposal

A. Question: If the plant takes the carcasses to a landfill, whose jurisdiction does this fall under?

Answer: This will be the responsibility of state or local authorities. FSIS personnel need only verify through plant records that the carcasses did in fact go to the landfill.

B. Question: Can the establishment dispose of the carcass prior to receiving lab results?

Answer: Yes. Because the animal was condemned at antemortem inspection, there is no requirement for establishments to hold carcasses. FSIS is recommending that establishments make arrangements to confirm negative results prior to these carcasses being rendered. This would not be an issue for carcasses going to incineration, alkaline digestion, or a lined landfill. Also, local sanitary codes are applicable.

C. Question: Can establishments remove carcasses from the premises outside of the official hours of operation without being sampled?

Answer: Yes. There are no regulations which would prohibit this from occurring. However, establishments remain subject to the FMIA denaturing requirements for such carcasses (21 USC 641). FSIS is committed to sample all available carcasses during established hours of operation.

VI. Sample Integrity

A. Question: Is the PHV responsible for determining whether the sample is of acceptable quality (i.e., whether autolysis has not occurred) before submitting a sample to the laboratory?

Answer: The PHV is responsible for the timely collection of and proper shipping of collected samples to the laboratory. PHVs are not responsible for making the determinations about the quality of the collected samples for their diagnostic suitability. If the collected samples have to be held prior to shipping they are to be held in cold storage, not frozen.

B. Question: When extracting the brain stem, what distance above and below the "V" (obex) do you allow?

Answer: The cut should be made approximately ½ to 1 inch above and below the obex.

C. Question: If the obex is unavailable, is there any other tissue which can be submitted for testing?

Answer: No, the obex is the only location we are currently testing.

D. Question: Can the obex be moistened to facilitate its entry into the tube?

Answer: No.

E. Question: Should the sample be washed/rinsed to remove blood clots?

Answer: No. APHIS prefers that blood clots are removed by hand and the sample be blotted with a paper towel.

F. Question: Is it necessary to attach an FSIS security seal to sample?

Answer: No.

G. Question: Because samples cannot be stored or passed through areas in which there is edible product, how can establishments store these samples?

Answer: Plants may have a dedicated refrigerator for samples in the inspection office or elsewhere that can be reached without passing through edible areas. Different options should be discussed during the awareness meeting, and could include, for example, use of a portable cooler.

H. Question: What if the brain stem is mutilated due to the method used to euthanize the animal?

Answer: Submit the sample and write on the sample form that the sample was mutilated prior to collection.

VII. Laboratory Results

A. Question: How long does it take to receive results after the brain sample is submitted?

Answer: The laboratories generally report the results 36 to 48 hours after the sample is shipped.

B. Question: Who will receive the results?

Answer: A report of the test results will be sent to the submitter, the AVIC, and the establishment, if requested.

C. Question: Will the results of the BSE test be posted on Laboratory Electronic Application for Results Notification (LEARN)?

Answer: No, not at this time.

D. Question: Other than reporting positive results, what will the laboratory report state?

Answer: The laboratory report may state one of the following: **"Not Detectable"** which indicates that the sample was tested and the results were negative; **"Location"** which could mean that the sample appeared to be a brain stem, but could not be identified as the obex; or **"Not Tested"** or **"Not Testable"** which means that the sample could not be recognized as a brain stem or that it was autolyzed.

E. Question: How may a carcass be disposed of when a result of "Not Tested" or "Not Testable" is received?

Answer: If a test was not conducted, plants may dispose of such carcasses by any available means such as inedible rendering, incineration, alkaline digestion, or movement to lined landfills in accordance with state or local codes.

VIII. Documentation

A. Question: What if the name and address of the owner are not available at the time of sampling?

Answer: The sample should be collected and submitted as soon as possible. The missing information can be sent at a later date when it becomes available (this information should be sent regardless of whether the sample results are positive or negative). This information should be made available in accordance with the recordkeeping requirements in 9 CFR part 320.

B. Question: Is it sufficient to identify a broker or auction house as the owner of the animal?

Answer: Every attempt should be made to attain the actual producer's name and address. However, if that cannot be obtained, identify a broker or auction house as the owner.

C. Question: Is filling out FSIS Form 6000-13 mandatory?

Answer: No. For antemortem condemned cattle, complete FSIS Form 6000-13 when requested by plant management. Consistent with their training for collection of BSE samples, PHV's are to maintain a file on each sampled animal. PHVs can use either a Form 6000-13, 6200-14, or 6150-1 to capture the condemnation Z-tag number of sampled animals. For plants with alternative procedures for off-site sampling, FSIS Form 6000-13 may be requested to facilitate correlations with the condemnation Z-tag number.

D. Question: Should animal identification (e.g., eartags, backtags) be collected and saved until sample results are received?

Answer: Yes, they should be saved in a plastic bag in association with the dedicated file. Do not send these items with the sample.

E. Question: How should "deads" be recorded in the "Clinical Signs" section of the APHIS form, Veterinary Services (VS) Form 10-4 - Supplemental Form?

Answer: Check the box marked "other" at the bottom-right portion of this section, and write in "dead" below it.

F. Question: Is the barcode placed on the copy of the condemnation form, or on the original?

Answer: On the copy (second sheet) that is maintained by FSIS. The original goes to the establishment.

G. Question: Is it mandatory to complete FSIS Form 5000-11, BSE Sampling Tracking Sheet?

Answer: Use of FSIS Form 5000-11 by PHVs who collect BSE samples is mandatory. The only acceptable version of this form is in Form Flow. The form is only to be used when FSIS personnel actually collect the sample. PHVs are to provide complete and accurate entries of all items on FSIS Form 5000-11. PHVs are to indicate the appropriate age to the best of their abilities. The forms should be either mailed or faxed to the Financial Processing Center (FPC). PHVs are not to submit duplicates because this would require FPC to verify the forms twice. Whether by mail or fax, PHVs can submit Form 5000-11 to the FPC on weekly basis. The form does not have to be submitted daily. Also, the PHV is not to submit other forms (e.g., FSIS Form 6000-13 or VS Form 10-4) to FPC. PHVs that collect a sample during a reimbursable overtime period are to note this in the provided check box, not in the remarks section. Established forms or timesheets should continue to be completed for regular and overtime hours.

H. Question: Should a copy of FSIS Form 5000-11 be sent with the sample?

Answer: No.

I. Question: Can unused sets of barcodes be utilized at a later date?

Answer: Yes, unused entire sets of barcodes can be utilized for future samples. Since each set represents a unique number, use one set of barcodes for each sample. Do not use incomplete sets. Destroy incomplete sets.

IX. Sample Shipping

A. Question: If a sample is collected on a Saturday, Sunday, or holiday, should the sample be held?

Answer: Yes, the sample should be held until the next available Federal Express pick-up.

B. Question: When a sample is sent, will the laboratory automatically return the shipping container?

Answer: National Veterinary Services Laboratory (NVSL) will automatically return the shipping container. However, the other labs do not provide automatic returns.

Therefore, sufficient sampling supplies should be maintained by ordering through NVSL (Ames, IA).

C. Question: Should unused tubes be saved?

Answer: Yes. They can be used for subsequent sampling.

D. Question: What is the turnaround time on shipping containers sent to NVSL?

Answer: Approximately five days. In an emergency, APHIS can ship overnight.

E. Question: Are the fax forms available for requesting overnight delivery of shipping containers?

Answer: Yes. This form (BSE Kit and Instrument Order Form) is available on Outlook "All Public Folders/OFO/Technical Service Center/BSE Training Info."

F. Question: Can the same shipping container for samples from 2 different establishments be used?

Answer: Yes, as long as the paperwork and equipment (e.g., tubes) are separate and properly identified.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy, Program, and Employee Development

APHIS **Factsheet**

Veterinary Services June 2004

APHIS' Enhanced Surveillance Program for Bovine Spongiform Encephalopathy

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has undertaken an intensive animal health surveillance program for BSE. The program is designed as a one–time effort that will provide a snapshot of the domestic cattle population to help define whether BSE is present in the United States, and if so, help calculate at what level.

Experience in the Europe since the first BSE diagnosis has shown that testing high–risk cattle is the method most likely to identify BSE if it is present. APHIS' increased surveillance of the U.S. cattle population is designed to test as many cattle from the high–risk population as possible in a 12–to–18–month period. The program is tailored to collect the majority of samples from the following categories:

- Nonambulatory cattle;
- Cattle exhibiting signs of a central nervous system disorder;
- Cattle exhibiting other signs that may be associated with BSE, such as emaciation or injury; or,
- Dead cattle.

In order to reach as many high–risk cattle as possible, samples will be taken from the farm, slaughter facilities, rendering facilities, livestock auctions, veterinary clinics, and public health laboratories. The surveillance program will also include a limited number of random samples from apparently normal, aged animals. The sampling of apparently normal animals will come from the 40 U.S. slaughter plants that handle 86 percent of the aged cattle processed for human consumption each year in the United States. The carcasses from these animals will be held and not allowed to enter the human food chain until test results show the samples are negative for BSE.

Under the enhanced surveillance program, sampling 201,000 animals would allow APHIS to detect BSE at the rate of 1 positive in 10 million adult cattle at a 95 percent confidence level assuming that all of the positives are in the targeted high–risk population. If 268,500 animals were sampled, APHIS could detect BSE at the same rate at a 99 percent confidence level. In other words, the enhanced program could detect BSE even if there were only five positive animals in the targeted population in the entire country.

BSE surveillance samples will be tested at APHIS' National Veterinary Services Laboratories (NVSL) and at other network laboratories. Rapid–screen testing will be performed and any suspect samples will undergo confirmatory testing by other methods such as immunohistochemistry and/or Western Blot.

If additional cases of BSE are identified in the United States, the cattle owners would be compensated for any cattle taken as a result of the traceback/traceforward investigations. Based on what we know about transmission of BSE, APHIS would not be depopulating an entire herd. APHIS will only be looking for individual animals that may have been exposed at a young age to the same feed as the affected animal. Any quarantine of affected animals would be temporary and losses due to the investigation would be reimbursed.

USDA and the U.S. Department of Health and Human Services (HHS) have strong safeguards in place to prevent the spread of BSE in the United States. Since 1989, USDA has banned the import of live ruminants and most ruminant products from the United Kingdom and other countries having BSE. HHS prohibited the use of most mammalian protein in the manufacture of animal feed intended for cows and other ruminants.

Several safeguards are also in place to protect public health. Most importantly, USDA has taken action to ensure that the tissues associated with BSE from animals considered most likely to have the disease have been banned from the human food chain. USDA has also made sweeping changes in slaughter and processing establishments that further reduce any risk to public health.

BSE Surveillance Program Outreach

As part of the enhanced surveillance program, APHIS is reaching out to cattle producers, renderers, slaughter facility operators and others to encourage their participation. The goal of the enhanced surveillance program is to provide consumers, trading partners, and industry increased assurances about the safety of the U.S. cattle population. To reach this goal, it is essential that animals identified as high–risk cattle are reported in a timely fashion so that viable samples can be collected.

To report high–risk animals, as described above, call APHIS' toll–free number 1–866–536–7593. You will be connected to the Area Veterinarian in Charge and given instructions on how to proceed.

More information on the BSE surveillance program is available online at http://www.aphis.usda.gov/lpa/issues/bse/bse.html.

General information about BSE is available online at http://www.aphis.usda.gov/lpa/issues/bse/bse_gen-info.html.

APHIS **Factsheet**

Veterinary Services June 2004

APHIS' BSE Surveillance Program

Q. What is the new surveillance program for bovine spongiform encephalopathy?
A. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has implemented an intensive national surveillance program for bovine spongiform encephalopathy (BSE). The program is designed as a one–time effort that will provide a snapshot of the domestic cattle population to help define whether BSE is present in the United States, and if so help calculate at what level.

The goal of the program is to test as many cattle from the high–risk population as possible in a 12–18 month period. In order to reach as many high–risk cattle as possible, samples will be taken from the farm, slaughter facilities, rendering facilities, livestock auctions, veterinary clinics, and public health laboratories.

The surveillance program will also randomly sample apparently normal, aged animals. The sampling of apparently normal animals will come from the 40 U.S. slaughter plants that handle 86 percent of the aged cattle processed for human consumption each year in the United States.

Q. Why did APHIS implement this enhanced surveillance program?
A. After the diagnosis of a case of BSE in an imported animal, USDA adopted several new public health safeguards to bolster U.S. protections and encourage trading partners to recognize the minimal BSE risk presented by U.S. beef. The goal of the enhanced surveillance program is to provide consumers, trading partners, and industry increased assurances about animal health, specifically whether BSE exists in the U.S. cattle population and if so, at what level.

Q. How will the testing be conducted?
A. USDA personnel will collect samples from high–risk cattle and send the samples to an existing network of state and federal laboratories approved to conduct rapid-testing for BSE. If the sample is negative, no further testing will be conducted. If the sample is inconclusive, confirmatory testing will be conducted at APHIS' National Veterinary Service Laboratories (NVSL), the national BSE reference laboratory.

Q. What is an inconclusive result?
A. Inconclusive results are test results for which a negative result cannot be determined using a single test assay. Such results are not unexpected and are a normal component of most screening tests. These tests are designed to be extremely sensitive so as to detect any sample that could possibly be positive. An inconclusive sample would undergo confirmatory testing using immunohistochemistry (IHC), which is recognized internationally as the gold–standard for BSE testing, or other confirmatory tests.

Q. What if additional cases of BSE are identified?
A. There is a possibility that the enhanced surveillance program will identify additional cases of BSE. If 268,500 animals are sampled, APHIS could detect BSE at a rate of 1 in 10 million adult cattle at a 99 percent confidence level assuming that all of the positives are in the targeted high–risk popoluation. In other words, the enhanced program could detect BSE even if there were only five positive animals the targeted popolulation in the entire country.

If additional cases of BSE are identified in the United States, the cattle owners would be compensated for any cattle taken as a result of the trace-back/traceforward investigations. Based on what we know about transmission of BSE, APHIS would not be depopulating an entire herd. APHIS will be looking for individual animals that may have been exposed at a young age to the same feed as an affected animal. Any quarantine of affected animals would be temporary and losses due to the investigation would be reimbursed.

USDA and the U.S. Department of Health and Human Services (HHS) have strong safeguards in place to prevent the spread of BSE in the United States. Since 1989, USDA has banned the import of live ruminants and most ruminant products from the United Kingdom and other countries having BSE. HHS prohibited the use of most mammalian protein in the manufacture of animal feed intended for cows and other ruminants.

Several safeguards are also in place to protect public health. Most importantly, USDA has taken action to ensure that the tissues associated with BSE from animals considered most likely to have the disease have been banned from the human food chain. USDA has also made sweeping changes in slaughter and processing establishments that further reduce any risk to public health.

Q. What can APHIS' partners do to help?
A. APHIS will build upon established partnerships with State animal health officials and many different segments of industry to obtain as many samples as possible from the targeted high–risk cattle population. Samples will be collected from any of the following locations:

- State or Federally inspected slaughter establishments
- Custom–exempt slaughter establishments
- Farms
- Rendering facilities
- Veterinary diagnostic laboratories
- Animal feed slaughter facilities (pet food plants)
- Public health laboratories
- Veterinary clinics

APHIS needs cooperation from its many partners in this intensive surveillance program. To reach our goal, it is essential that animals identified as high–risk cattle are reported in a timely fashion so that viable samples can be collected.

To report high–risk animals, call APHIS' toll–free number 1–866–536–7593. You will be connected to the Area Veterinarian in Charge and given instructions on how to proceed.

Q. What are high–risk animals?
A. Experience in Europe has shown that testing high–risk cattle is the method most likely to identify BSE if it is present. Therefore, USDA has tailored its surveillance program to collect the majority of samples from the following categories:

- Non–ambulatory cattle;
- Cattle exhibiting signs of a central nervous system disorder;
- Cattle exhibiting other signs that may be associated with BSE, such as emaciation or injury; and
- Dead cattle.

USDA personnel will also sample all cattle condemned on ante–mortem inspection by USDA's Food Safety and Inspection Service.

Q. Where can individuals get more information?
A. More information on the BSE surveillance program is available online at http://www.aphis.usda.gov/lpa/issues/bse/bse.html.

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

March 30, 2004

VETERINARY SERVICES MEMORANDUM NO. 580.4

Subject: Procedures for Investigating a Suspected Foreign Animal Disease/Emerging Disease Incident (FAD/EDI)

To: Directors, Veterinary Services (VS)
Area Veterinarians in Charge, VS
National Veterinary Services Laboratories (NVSL) Director
Regional Directors (RD)
International Services (IS)

I. PURPOSE

This memorandum revises VS policy and procedures for FAD/EDI investigations.

II. CANCELLATION

VS Memorandum No. 580.4, dated December 31, 2001, is hereby canceled.

III. GENERAL

The Area Veterinarian in Charge (AVIC) or the AVIC's designee (hereafter referred to as AVIC) will initiate a timely investigation of all reported suspect FAD/EDIs and assign the most readily available Foreign Animal Disease Diagnostician (FADD) to complete an investigation.

IV. SPECIFIC INSTRUCTIONS

A. Investigation Procedures

The following section lists the responsibilities of AVICs and FADDs regarding FAD/EDI investigation procedures

1. **AVIC Responsibilities** - After the report of a suspect FAD/EDI, the responsible AVIC must:

- Prepare a case report that includes as much of the following information as possible: The Reference Control Number (see Attachment II); supected disease condition and species affected; date of initial report; species, breed, or type and number of animals on premises; number of animals affected and duration of illness; history of the name and telephone number of owner and/or manager; premises address; name and telephone number of person and/or private practioner reporting the disease; and, for State or military FADDs, provide the web site address for access to the Emergency Management Response System (EMRS) FAD/EDI investigation database.

- Ensure that an investigation is initiated (FADD has contacted affected premises) **within 8 hours** of receiving the initial report and the inspection of animals is done as soon as possible;

- Ensure that the appropriate Priority (1, 2, 3, or A) for the laboratory has been assigned when the FADD has completed the initial investigation. **Contact Emergency Programs (EP) staff immediately by telephone when Priority 1 or Priority A has been assigned to a specimen (see Attachment I);**

- Follow established reporting procedures (see Section IV, B; page 3);

- Ensure that preliminary information is entered into EMRS Investigation summary and Herd Exam form;

- Monitor investigation and follow-up until there is a determination of no FAD/EDI;

- Ensure that the Status type is changed to "Diagnosis Neg for FAD" to close a case;

- Ensure that the laboratory results are entered into the EMRS Sample/Lab Report Form; and

- Forward preliminary and final results to the FADD for owner/manager and veterinarian notification as well as appropriate State or Tribal officials when results are provided to the Area Office.

2. **FADD Responsibilities** - After the AVIC assigns the case to the FADD, the FADD must:

- Immediately contact the private veterinarian or owner/producer and initiate an investigation and review EMRS FAD/EDI Investigation Summary information and Herd Exam Form prior to performing the investigation;

- Assess the situation, including physical exam findings, vaccination history, herd health practices, etc.;

- Formulate a list of differential disease diagnoses;

- Contact the Foreign Animal Disease Diagnostic Laboratory (FADDL) or National Veterinary Services Laboratories (NVSL) personnel and use their expertise to ensure the collection of appropriate laboratory specimens;

- Conduct a thorough epidemiological investigation to include, at least, information about the duration of illness; potential exposure(s); temperatures from live animals that were sampled; vaccination history; animal movement; and human health (for possible zoonoses);

- Contact the AVIC to report findings of the investigation immediately after the investigation is complete, and in consultation with the AVIC, determine the laboratory priority for diagnostic speciments based upon investigative findings;

- Inform the AVIC of a decision to quarantine;

- Contact the appropriate laboratory by phone **prior** to shipping samples (regardless of priority) to provide priority number, Airbill tracking number, and day of arrival;

- Ship diagnostic specimens in good condition and in proper packaging to the proper laboratory (either FADDL, Plum Island, New York, or NVSL-Ames, Ames, Iowa -- see Attachments III and IV);

- Complete the EMRS FAD/EDI Herd Exam Form and all appropriate follow-up forms immediately after submitting laboratory samples;

- E-mail the EMRS FAD/EDI Investiation report to the AVIC when data entry is completed;

- Follow up with the AVIC to ensure closure of investigations within a week of receiving final laboratory results, along with any "follow-up" information, that rules out an FAD/EDI.

B. Reporting and Notification Procedures

A complete report is necessary whether or not diagnostic specimens are collected and submitted.

1. **AVIC Reporting Responsibilities** – The AVIC must:

- **Immediately contact EP staff by telephone for all possible Priority 1 and Priority A cases (see Attachment I);**

- Notify the Regional office;

- Inform, and consult with, the State Veterinarian and Tribal official;

- Ensure that a completed electronic EMRS FAD/EDI Investigation Summary and its herd exam and lab submission forms are forwarded to the State Veterinarian's office.

2. **FADD Reporting Responsibilities** - The FADD must:

- Report initial findings of the investigation, as soon as the investigation is complete, to the AVIC or the AVIC's designee;
- Immediately notify the appropriate laboratory (regardless of priority) that samples have been collected and are on their way to NVSL-Ames or FADDL;
- Notify the necessary State or Tribal officials to initiate quarantine, if appropriate;
- Update an electronic EMRS FAD/EDI Investigation Summary with verified information and GPS coordinates;
- Complete the Herd Exam Form;
- Initiate a Lab Submission Form;
- Complete VS Form 10-4, to include the Referral Control Number, contained in the lab specimen box that will be shipped to the appropriate laboratory;

The FADD **must** provide the following information (when available) on VS-Form 10-4 so that the laboratory diagnostician has all of the information he or she needs:

- Referral Control Number;
- Airbill tracking number (if samples were sent);
- City, county, State of premises under investigation;
- Name of the owner/manager;
- Species, breed, or type, and number of animals on premises;
- History on the disease (the number of affected animals, species affected, morbidity, mortality, signs of disease, duration of disease, identify if multiple premises are affected, associated human illness, etc.);
- Presumptive field diagnosis with differentials;
- Priority of the samples.

- By e-mail, send the AVIC the updated EMRS FAD/EDI Investigations Summary before specimens arrive at the designated laboratory;

If the FADD is unable to immediately e-mail the FAD/EDI Investigation Summary, he or she should contact the AVIC to provide the Airbill tracking number, obtain a priority number, and indicate to what laboratory the specimens were submitted (see Attachment II). As additional information is obtained, it must be added to the current electronic EMRS FAD/EDI investigation report.

- Consult and follow up with the veterinary practioner and owner/manager to keep them informed of the investigation process.

4. Using EMRS for Reporting and Tracking

EMRS must be used throughout the investigation. The AVIC, FADD, and laboratory personnel must enter all information specified in this document and any other pertinent information that emerges during the investigation into the EMRS.

5. Laboratory Reporting

- NVSL-Ames and/or FADDL will report preliminary and final laboratory results to the AVIC and EP Staff for all specimens, regardless of the assigned Priority number.

- The FADD, after consultation with the AVIC, will inform the owner/manager and referring veterinarian of the laboratory test results as soon as possible once test results have been obtained. The AVIC will ensure that all laboratory results are listed on Sample/Lab Report form.

- **The NVSL Director will immediately report *positive or suspect* laboratory findings to the Deputy Administrator's Office and Associate Deputy Administrator for Emergency Management.** EP Staff will coordinate a conference call with the Deputy Administrator's Office, RD, AVIC, FADD, State Veterinarian, appropriate laboratory personnel, and the Emergency Management Leadership Team (EMLT) for future action planning. This conference call will occur within 2 hours of EP staff's notification.

C. Case Diagnosis

Classifying an FAD/EDI investigation as a "presumptive case" or "confirmed case" is the responsibility of the Deputy Administrator.

D. Case Closure

- Investigations for suspected FAD/EDIs will be closed by the AVIC and/or the State Veterinarian.

- Cases should **not** be closed until a follow-up visit or phone call has been made by the FADD and the owner/manager is informed of the laboratory results.

- The electronic EMRS FAD/EDI Investigation Summary form will be used to record all follow-up information, laboratory results, quarantine release dates, etc.
- The AVIC should ensure that a Sample/Lab Report form is completed. The form should state the laboratory results.
- If the laboratory results are negative for an FAD/EDI investigation, following consultation and concurrence with the FAD and others, the AVIC will open the Status Form to designate the final diagnosis for the case and close the case.

V. INQUIRY

Any questions regarding these procedures should be directed to the EP Staff (Attachment I).

for :
W. Ron DeHaven
Deputy Administrator
Veterinary Services

5 Attachments:
Emergency Programs Contact Information
EMRS FAD/EDI Investigation Reporting Instructions
FAD/EDI Diagnostic Specimen Submission Procedures
FAD/EDI Specimen Shipping Information
A: To FADDL
B: To NVSL-Ames
FedEx® USA Airbill

Attachment I

EMERGENCY PROGRAMS' CONTACT INFORMATION

BUSINESS HOURS (8:00 a.m. to 5:00 p.m., Eastern Time, Monday - Friday):

MAIN OFFICE NUMBER	**301-734-8073**
TOLL-FREE NUMBER	**800-940-6542**

AFTER BUSINESS HOURS, HOLIDAYS, WEEKENDS:

DR. TRACY DUVERNOY	240-508-8619 (cell)	301-593-6350 (home)
DR. AIDA BOGHOSSIAN	240-508-9748 (cell)	301-776-3266 (home)
DR. RANDY CROM	240-508-9753 (cell)	202-659-0321 (home)
DR. JOE ANNELLI	240-508-9747 (cell)	410-750-9743 (home)

EP will immediately notify the Regional Directors and Associate Regional Directors of changes in these after business hours contact numbers.

Attachment II

EMERGENCY MANAGEMENT RESPONSE SYSTEM
FAD/EDI INVESTIGATION REPORTING INSTRUCTIONS

INTRODUCTION: The Lotus Notes database called the FAD/EDI Investigation Reporting Form has been replaced with the Emergency Management Response System (EMRS) "Routine FAD/EDI Reporting" database. This database can capture and track information about FAD/EDI investigations and has many advantages over the previous system. It is accessed through the Web (http://www.aphis.usda.gov/vs/ep/emrslogin.html) and allows anyone with a user ID and password to view or enter investigations from their State. **All entries are confidential.** The reporting process should run smoothly through the use of the online tutorial and the following actions:

INITIAL CALL**:** The AVIC will initiate investigations. He or she will create a new "Investigation Summary" by first "Creating a Premises ID" using the address of the premises under investigation. First, enter the premises ID number, the referral control number, animal location data, and premises owner/manager address data. Second, after saving the Investigation Summary, the Case Coordinator (AVIC) part of the form will appear and is assigned to the AVIC. Third, a Herd Exam Follow-up form is initiated and the investigation is assigned to a FADD; other data obtained from the initial call is entered. (If there is any difficulty in creating the Prem ID, put the Referral Control Number [RCN] in both the Prem ID and RCN location. The Prem ID can be created at another time.)

DATA ENTRY**:** Once the FADD has completed the investigation, the findings should be entered into the database as soon as possible, with attention given to the Herd Exam Form, Lab Submission Form, and all applicable follow-up forms .

NOTIFICATION: The FADD should email the EMRS FAD/EDI Investigation Summary to the AVIC. The FAD/EDI mailing group (includes the NVSL-Ames, FADDL, Regional Directors, and EP) will automatically be sent when the FAD/EDI Investigation Summary is completed. Since EP Staff monitors reports daily, it is unnecessary to call for notification. **However, for all potential Priority 1 or A cases, the AVIC must phone the EP Staff immediately.**

REVIEW PROCESS: Various persons can be granted access to an EMRS Investigation Summary and allowed to edit, add, or delete information pertaining to the investigation. The individuals granted access to the document should be from the Area office and/or the FADD.

FOLLOW-UP FORMS: This feature allows for the accurate chronology of the investigation. These forms are used to input additional information and the reexamination of animals. The AVIC **must** complete the Lab Submission Form and

Lab Sample Report form when closing the investigation; it should include final laboratory results.

DISPOSITION AND CONTROLS: This feature allows the entry of quarantine and closing information. The AVIC **must** complete a Disposition and Controls form when closing the investigation; it should include a final diagnosis and further actions taken (e.g., quarantine release).

MAINTENANCE: The AVIC must maintain the FAD/EDI investigations for their States. This includes reviewing investigation reports to ensure all pertinent information is recorded and validated, cases are closed promptly, and to ensure that Lab Report Information forms are completed when laboratory results are received. If the FADD does not have immediate access to this electronic form, he or she must supply a verbal or hard copy report to the AVIC.

PREMISES ID NUMBER: A unique premises ID number can be created and entered on the Investigation Summary form. To obtain the premises ID number, enter the premises address information into the "Premises ID Creation" module within the EMRS. If there are any problems with "Premises ID Creation," use the Referral Control Number as a temporary number for this variable and the EMRS Team will assist to obtain a Premises ID Number after the FAD/EDI Investigation has begun.

REFERRAL CONTROL NUMBER: The AVIC is to assign the 8-digit referral control number (RCN) for each suspect FAD/EDI investigation. The RCN must be entered on the Investigation Summary form and is to be assigned as follows:

- First 2 digits represent the fiscal year (e.g., 04) in which the investigation will take place.
- Next 2 digits represent the State (e.g., California = CA) in which the primary premises investigated is located.
- Next 4 digits specify the investigation number (e.g., 0005) for the fiscal year.

In this example, "04CA0005" would represent the fifth investigation conducted at a premises in the State of California during fiscal year 2004. (Please do **not** add an additional suffix letter (e.g., E or W) to the RCN to indicate the region.)

Attachment III

FAD/EDI DIAGNOSTIC SPECIMEN PRIORITY DESIGNATION AND SUBMISSION PROCEDURES

When the FADD has completed the initial investigation, he or she must contact the AVIC to obtain a priority number that will indicate to the laboratory the urgency for completing the diagnostic testing of the samples being submitted. The AVIC will use the below definitions for assigning a priority: 1, 2, 3, or A. **In all Priority 1 or A cases, EP staff is to be notified by phone prior to shipping specimens.** Emergency Programs staff is available for consultation and can assist in assigning the priority. Laboratory priority is determined by evaluating the complete situation surrounding the investigation, including the disease condition observed (differential diagnosis, species affected, morbidity, mortality, and epidemiologic findings), the potential impact on commerce (including international trade), and any other potentially significant circumstances of which the AVIC or FADD has knowledge. The assignment of Priority may entail additional communication with other key officials including those at NVSL-Ames, FADDL, and the State Veterinarian. Mark the priority number on the label affixed outside the shipping container, on the VS 10-4 submission form, and in the EMRS Lab Submission Form.

Priority 1: This priority should be used when prompt laboratory diagnostic information is required because known investigation information makes it **highly likely** that the observed condition is an FAD/EDI.

In addition, FADDL or NVSL-Ames is to be notified **by phone prior** to shipping specimens. Specimens will be unpacked, examined, and diagnostic studies begun immediately at FADDL or NVSL-Ames, including evenings, Saturdays, Sundays, and holidays. Counter-to-counter air may need to be used for Sunday, holiday, or certain Saturday shipments. In extreme cases, Priority 1 samples will be hand carried via courier to the appropriate laboratory; overtime is used as necessary. Results are reported by telephone to the NVSL Director, Director of Emergency Programs, and the AVIC immediately upon completion of initial laboratory results.

If a courier is to transport the samples, the courier must first notify FADDL or NVSL-Ames, as soon as possible, the flight details so that the FADDL representative can meet the courier at the Airport. The closest Airport to Plum Island is approximately 60 miles west at the Long Island/MacArthur Airport. JFK International or LaGuardia Airports are approximately 110 miles west from Plum Island.

Because of heightened security at FADDL laboratories, if samples are to be hand-carried to these laboratories, the courier **must phone FADDL** in advance. Safety and Security personnel at FADDL must be alerted in advance and the courier **must** be met by a FADDL representative at the security gates (regardless of the time of day or night).

For samples that are not hand carried, but that need to arrive at FADDL earlier than an overnight FedEx® delivery, shipment **must** be via counter to counter service, airport to airport (e.g., American Airlines Priority Parcel Service). Check with airlines for this service in your area. FADDL must be notified by phone (phone numbers are included in Attachment IV). If after business hours, weekends or holidays, leave a complete message on the recording to include name of shipper, origin, estimated time of arrival of the flight, airline name and flight number, origin and the AirBill tracking number (critical to track the package) along with the name of the caller and a call-back number so that the information can be verified.

Priority 2: This priority is used when known investigation information makes it **possible** that the observed condition is an FAD/EDI, but cannot be distinguished from an endemic disease/condition; and rapid laboratory diagnostic information is necessary. Specimens are unpacked, examined, and diagnostic studies begun immediately if the shipment reaches the laboratory before the close of the work day. Overtime can be used to finish the examination. Specimens arriving after the close of the work day will be examined first thing the following day. Specimens received Saturday will be processed that day **only** with prior notification and discussion with the laboratory. The laboratory will report results by FAX to EP and the AVIC immediately upon completion of initial laboratory results.

Priority 3: This priority is used when known investigation information makes it **unlikely** that the observed condition is an FAD/EDI and cannot be distinguished from an enzootic disease or condition. The disease is considered most likely an enzootic disease or condition due to epidemiological factors (e.g., season, previously diagnosed enzootic disease in the adjacent area, etc.); laboratory diagnostic information is used to verify if the condition is an FAD/EDI. Specimens will be processed according to accession order as received. Overtime will **not** be used for these investigations. This priority is also used for routine surveillance samples.

Priority A: This priority will be used for those situations where:

1) Any animals in commerce are being held (delayed) pending the results of testing for an FAD/EDI, whether or not it is likely that the observed condition is due to an FAD/EDI. Examples of "animals in commerce" could include, but are not necessarily limited to: animals at a slaughter facility, animals at a market or auction, or animals at an international export facility.
2) Other known or potential circumstances surrounding the investigation indicate that it would be prudent to obtain laboratory test results as rapidly as possible, regardless of the likelihood of the presence of an FAD/EDI.

In addition, FADDL or NVSL-Ames is to be notified **by phone prior** to shipping specimens. Specimens will be unpacked, examined, and diagnostic studies begun immediately at FADDL or NVSL-Ames, including evenings, Saturdays, Sundays, and holidays. Counter-to-counter air may need to be used for Sunday, holiday, or certain Saturday shipments. In extreme cases, Priority 1 samples will be hand carried via courier to the appropriate laboratory; overtime is used as necessary. Results are

reported by telephone to the NVSL Director, Director of Emergency Programs, and the AVIC immediately upon completion of initial laboratory results.

If a courier is to transport the samples, the courier must first notify FADDL or NVSL-Ames, as soon as possible, the flight details so that the FADDL representative can meet the courier at the Airport. The closest Airport to Plum Island is approximately 60 miles west at the Long Island/MacArthur Airport. JFK International or LaGuardia Airports are approximately 110 miles west from Plum Island.

Because of heightened security at FADDL laboratories, if samples are to be hand-carried to these laboratories, the courier **must phone FADDL** in advance. Safety and Security personnel at FADDL must be alerted in advance and the courier **must** be met by a FADDL representative at the security gates (regardless of the time of day or night).

For samples that are not hand carried, but that need to arrive at FADDL earlier than an overnight FedEx® delivery, shipment **must** be via counter to counter service, airport to airport (e.g., American Airlines Priority Parcel Service). Check with airlines for this service in your area. FADDL must be notified by phone (phone numbers are included in Attachment IV). If after business hours, weekends or holidays, leave a complete message on the recording to include name of shipper, origin, estimated time of arrival of the flight, airline name and flight number, origin and the AirBill tracking number (critical to track the package) along with the name of the caller and a call-back number so that the information can be verified.

Specimen Submission Procedures

The FedEx® Airbill tracking number is used to trace the specimens from the field to the laboratory. **Please make sure that the Airbill tracking number is noted on the EMRS FAD/EDI Investigation Summary as well as on VS Form 10-4.** All diagnostic specimens for a suspected FAD/EDI must be shipped in a properly labeled box and sent to either NVSL-Ames or FADDL. (Note: packages must meet standards set by the national ground transport regulations and the International Air Transport Association: packaging can withstand a drop of 27 feet, packaging is waterproof, and all packages are clearly marked to specify their contents.)

The chart below identifies the laboratory to which various types of specimens should be sent.

Type of Specimens:	FADDL	NVSL-Ames
Ruminants		
BSE suspects		**PL**
Heartwater suspects		**PL**
All other ruminant specimens	**X**	
Avian		**DVL**
Entomologic specimens, all species		**PL**
Equine (including African horsesickness suspects)		**DVL**
Swine		
Classical swine fever suspects	**X**	
African swine fever suspects	**X**	
Blue eye paramyxovirus suspects		**DVL**
Teschen-Talfan disease suspects		**DVL**
All other swine specimens	**X**	

NVSL Departments: DVL- Diagnostic Virology; PL- Pathobiology

It is strongly recommended that if classical swine fever or African swine fever is suspected, other non-exotic diseases should be included in the differential diagnosis. Sample specimens should be **split** with one set sent to FADDL and another set to NVSL-Ames. The specimens submitted to NVSL-Ames are to be clearly marked "**Hold until cleared for exotic disease by FADDL.**" Notify FADDL and NVSL-Ames that samples are being shipped.

If more than one laboratory unit at NVSL-Ames is requested to perform diagnostic testing (e.g., virology, bacteriology, pathobiology), samples should be split by the FADD and labeled for each laboratory unit.

- All specimens should be packaged according to biosecurity procedures [see http://www.aphis.usda.gov/vs/nvsl/faddlmethodsforshipping.htm for a more specific description], identified, chilled with freezer gel-packs, and properly boxed for transit to the laboratory. **DO NOT USE DRY ICE or FREEZE SAMPLES.**
- A completed and legible Specimen Submission Form (VS Form 10-4) must accompany all diagnostic specimens. Include a Specimen Submission Form in each box of specimens sent to NVSL-Ames and FADDL. Please attach a Specimen Submission Form Continuation Sheet (VS Form 10-4A) to account for all specimens included in the shipment and fully describe all findings and other relevant information.
- The Specimen Submission Form (VS Form 10-4) is to be placed on top of the styrofoam lid under the cardboard top of the box, **not** inside the styrofoam container with samples.

- **Do not** write "formalin" or "formaldehyde" on the form or shipping container. (The concentrations used [less than 10% formalin] do not constitute hazardous materials).
- To request extra media, contact the NVSL Shipping Department at (515) 663-7530.

If there are any questions regarding shipping FAD/EDI investigation specimens via FedEx®, contact EP Staff or call FedEx® directly at (800) 463-3339.

Attachment IV - A

FAD/EDI Specimen Shipping Information to FADDL

Note: Because FADDL is located on an island, it is essential to call FADDL (631-323-3256) **every time** prior to shipping so FADDL can arrange for package pick up **regardless of Priority**.

For all deliveries of **Priority 2 or 3**, mark the "HOLD WEEKDAY" box on the right side of the FedEx® Airbill (see attached FedEx® USA Airbill example).

For Priority 2 samples shipped on Fridays, mark the "HOLD SATURDAY" box. It is imperative that laboratory personnel are contacted to inform them of samples arriving on Saturday. Arrangements have to be made for the samples to be picked up.

Information to be included on the FedEx® Airbill

Specimens being sent to **USDA/APHIS/Foreign Animal Disease Diagnostic Laboratory** must be shipped via FedEx® to:

USDA/APHIS/VS/NVSLFADDL
40550 RT 25
Orient, NY 11957

On the FedEx® form, write on the line under this address to Hold at:
579 Edwards Avenue
Calverton, NY 11933

The additional Calverton address allows FADDL to pick up the package as soon as possible in the morning, therefore allowing a full day of laboratory procedures.

++++++++++++++++++++

When shipping, please remember the following:

- Use the Area Billing number for the sender's FedEx® account number obtained from the AVIC;
- On the FedEx® Airbill, Internal Billing Reference (Section 2), write the Area Office's accounting code obtained from the AVIC or Designee;
- Check the FedEx® Priority Overnight box;
- Keep the sender's copy of the Airbill for your records:
- The FADD or AVIC must notify FADDL by phone every time samples are being sent.

Notification Telephone Numbers

During weekday business hours (8:30 a.m. to 4:15 p.m., Eastern Time) call **631-323-3256 or -3206**.

After hours or on weekends call the FADDL Cell Phone numbers of **Tom McKenna 240-508-9882, Samia Shawky 631-375-5314 or Barry Latney 631-871-3112.** If you have to leave a message, include your name and a call-back number.

FedEx Express *USA Airbill* **FedEx Tracking**

From

Sender's FedEx
Date _____ Account Number _____

Sender's
Name _____ Phone (___) _____

Company _____

Address _____

City _____ State _____ Zip _____

2 Your Internal Billing Reference

3 To
Recipient's
Name _____ Phone **(631) 323-3256**

Company **USDA/APHIS/FADDL**

Address **Orient Point Warehouse, Route 25**
To "HOLD" at FedEx location, print FedEx address.

579 Edwards Ave., Calverton, NY 11933

City **Orient Point** State **NY** Zip **11957**

4a Express Package Service

☐ FedEx Priority Overnight ☐ FedEx Standard Overnight ☐ FedEx First Overnight

☐ FedEx 2Day ☐ FedEx Express Saver ☐ NEW FedEx Extra Hours

4b Express Freight Service

☐ FedEx 1Day Freight ☐ FedEx 2Day Freight ☐ FedEx 3Day Freight
Call for Confirmation

5 Packaging
☐ FedEx Envelope ☐ FedEx Pak ☐ Other Pkg.

6 Special Handling
☐ **SATURDAY Delivery** ☐ **SUNDAY Delivery** ☒ **HOLD Weekday** ☐ **HOLD Saturday**
RESTRICTIONS **RESTRICTIONS** **at FedEx Location** **at FedEx Location**

Does this shipment contain dangerous goods?
One box must be checked.
☐ No ☐ Yes ☐ Dry Ice ___ x ___ kg ☐ Cargo Aircraft Only
Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours.

7 Payment ***Bill to:***

☐ Sender ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

FedEx Acct No.
Credit Card No.

Total Packages	**Total Weight**	**Total Declared Value**
		$.**00**

8 Release Signature

Attachment IV - B

FAD/EDI Specimen Shipping Information to NVSL-Ames

Information to be included on the FedEx® Airbill

Specimens being sent to **USDA/APHIS**/National Veterinary Services Laboratory in Ames must be shipped via FedEx® to:

USDA, NVSL
1800 Dayton Road
Ames, Iowa 50010

When shipping, please remember the following:

- Use the Area Billing number for the sender's FedEx® account number obtained from the AVIC;
- On the FedEx® Form, Internal Billing Reference (Section 2), write the Area accounting code obtained from the AVIC;
- Check the FedEx® Priority Overnight box;
- Saturday delivery should be marked for Priority 1 and 2 samples sent on Friday;
- Keep the sender's copy of the Airbill for your records.
- The FADD or AVIC must notify NVSL-Ames by phone that samples are being sent.

Notification Telephone Numbers

Weekday business hours (8:00 a.m. - 4:30 p.m. Central Time) call the appropriate laboratory:

Diagnostic Virology	**515-663-7551**
Pathobiology	**515-663-7521**
Bacteriology	**515-663-7563**

After hours or on weekends call the general National Animal Disease Center / NVSL at **515-663-7200**. The security personnel will call the appropriate NVSL person and give them a phone number to call the FADD.